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1 **TITLE I—ESTABLISHMENT OF**
 2 **PART B PAYMENT RULES FOR**
 3 **NEGOTIATION ELIGIBLE**
 4 **DRUGS AND BIOLOGICALS.**

5 **SEC. 101. ESTABLISHMENT OF PART B PAYMENT RULES**
 6 **FOR NEGOTIATION ELIGIBLE DRUGS AND**
 7 **BIOLOGICALS.**

8 Section 1847A of the Social Security Act (42 U.S.C.
 9 1395w-3a) is amended—

10 (1) in paragraph (1)—

1 (A) in the matter preceding subparagraph
2 (A), by striking “Subject to paragraph (7)” and
3 inserting “Subject to paragraphs (7) and (9)”
4 ;

5 (B) in subparagraph (B), by striking at
6 the end “or”;

7 (C) in subparagraph (C), by striking the
8 period at the end and inserting “; or”; and

9 (D) by adding at the end the following new
10 subparagraph:

11 “(D) in the case of a negotiation eligible
12 drug or biological, the maximum allowable cost
13 determined under paragraph (9).”; and

14 (2) by adding at the end the following new
15 paragraph:

16 “(9) RULES FOR NEGOTIATION ELIGIBLE
17 DRUGS AND BIOLOGICALS.—

18 “(A) NOTIFICATION OF MANUFACTURERS
19 OF NEGOTIATION ELIGIBLE DRUGS AND
20 BIOLOGICALS.—

21 “(i) IN GENERAL.—Not later than
22 180 days after the date of the enactment
23 of this paragraph, the Secretary shall no-
24 tify each manufacturer of each negotiation

1 eligible drug or biological that is subject to
2 negotiation for payment under this part.

3 “(ii) NEGOTIATION ELIGIBLE DRUG
4 OR BIOLOGICAL.—In this paragraph, the
5 term ‘negotiation eligible drug or biological’
6 means a single source drug or biological
7 (as defined in subparagraph (C)) for
8 which each of the following have expired:

9 “(I) The period of regulatory
10 data protections or exclusivity granted
11 for such drug or biological (including
12 for new chemical entities, biologics,
13 orphan drugs, pediatric formulations,
14 and clinical trials).

15 “(II) Subject to the succeeding
16 sentence, the period of any patents
17 issued for such drug or biological up
18 to 1 year after the approval of such
19 drug or biological. In the case of small
20 molecule product that is a such a
21 drug or biological, the period of any
22 patents listed in the publication, Ap-
23 proved Drug Products With Thera-
24 peutic Equivalence Evaluations (re-
25 ferred to as the ‘Orange Book’).

1 “(B) NEGOTIATION.—

2 “(i) IN GENERAL.—The Secretary and
3 the manufacturer of a negotiation eligible
4 drug or biological shall during the negotia-
5 tion period negotiate a maximum allowable
6 cost for such drug or biological. In the case
7 that the Secretary and the manufacturer
8 do not determine a maximum allowable
9 cost for such drug or biological, the Sec-
10 retary shall determine the maximum allow-
11 able cost for such drug or biological at an
12 amount that is at least 65 percent and not
13 more than 75 percent of the average sales
14 price of such drug or biological.

15 “(ii) MAXIMUM ALLOWABLE COST.—
16 In this subparagraph, the term ‘maximum
17 allowable cost’ means the amount agreed
18 to by the Secretary and the manufacturer
19 of a negotiation eligible drug or biological
20 for a unit of such drug or biological that
21 is not less than 65 percent and not more
22 than 75 percent of the lowest average sales
23 price of such drug or biological for the pre-
24 ceding 1-year period.

1 “(C) SINGLE SOURCE DRUG OR BIOLOGI-
2 CAL.—For purposes of this paragraph, the term
3 ‘single source drug or biological’ means—
4 “(i) a drug or drug product that—
5 “(I) is approved under section
6 505(c) of the Federal Food, Drug,
7 and Cosmetic Act and is marketed
8 pursuant to such approval; and
9 “(II) is not the listed drug for
10 any drug that is approved under sec-
11 tion 505(j) and is marketed pursuant
12 to such approval; or
13 “(ii) a biological product that—
14 “(I) is licensed under section
15 351(a) of the Public Health Service
16 Act, including any product deemed to
17 be licensed under such section pursu-
18 ant to section 7002(e)(4) of the Bio-
19 logics Price Competition and Innova-
20 tion Act and is marketed pursuant to
21 section 351 of the Public Health Serv-
22 ice Act; and
23 “(II) is not the reference product
24 fro any biological product that is li-

1 censed and is marketed pursuant to
2 such section of such Act.”.

3 **TITLE II—MEDICARE**

4 **Subtitle A—Part B**

5 **SEC. 201. INCLUSION OF VALUE OF COUPONS IN DETER-**
6 **MINATION OF AVERAGE SALES PRICE FOR**
7 **DRUGS AND BIOLOGICALS UNDER MEDICARE**
8 **PART B.**

9 Section 1847A(c) of the Social Security Act (42
10 U.S.C. 1395w–3a(c)) is amended—

11 (1) in paragraph (3)—

12 (A) by striking “DISCOUNTS.—In calcu-
13 lating” and inserting “DISCOUNTS TO PUR-
14 CHASERS AND COUPONS PROVIDED TO PRI-
15 VATELY INSURED INDIVIDUALS.—

16 “(A) DISCOUNTS TO PURCHASERS.—In
17 calculating”; and

18 (B) by adding at the end the following new
19 subparagraph:

20 “(B) COUPONS PROVIDED TO REDUCE
21 COST-SHARING.—For calendar quarters begin-
22 ning on or after July 1, 2024, in calculating the
23 manufacturer’s average sales price under this
24 subsection, such price shall include the value
25 (as defined in paragraph (6)(J)) of any coupons

1 provided under a drug coupon program of a
2 manufacturer (as those terms are defined in
3 subparagraphs (K) and (L), respectively, of
4 paragraph (6)).”; and

5 (2) in paragraph (6), by adding at the end the
6 following new subparagraphs:

7 “(J) VALUE.—The term ‘value’ means,
8 with respect to a coupon (as defined in sub-
9 paragraph (K)), the difference, if any, be-
10 tween—

11 “(i) the amount of any reduction or
12 elimination of cost-sharing or other out-of-
13 pocket costs described in such subpara-
14 graph to a patient as a result of the use
15 of such coupon; and

16 “(ii) any charge to the patient for the
17 use of such coupon.

18 “(K) COUPON.—The term ‘coupon’ means
19 any financial support that is provided to a pa-
20 tient, either directly to the patient or indirectly
21 to the patient through a physician, prescriber,
22 pharmacy, or other provider, under a drug cou-
23 pon program of a manufacturer (as defined in
24 subparagraph (L)) that is used to reduce or
25 eliminate cost-sharing or other out-of-pocket

1 costs of the patient, including costs related to
2 a deductible, coinsurance, or copayment, with
3 respect to a drug or biological, including a bio-
4 similar biological product, of the manufacturer.

5 “(L) DRUG COUPON PROGRAM.—

6 “(i) IN GENERAL.—Subject to clause
7 (ii), the term ‘drug coupon program’
8 means, with respect to a manufacturer, a
9 program through which the manufacturer
10 provides coupons to patients as described
11 in subparagraph (K).

12 “(ii) EXCLUSIONS.—Such term does
13 not include—

14 “(I) a patient assistance program
15 operated by a manufacturer that pro-
16 vides free or discounted drugs or
17 biologicals, including biosimilar bio-
18 logical products, (through in-kind do-
19 nations) to patients of low income; or

20 “(II) a contribution by a manu-
21 facturer to a nonprofit or Foundation
22 that provides free or discounted drugs
23 or biologicals, including biosimilar bio-
24 logical products, (through in-kind do-
25 nations) to patients of low income.”.

1 **SEC. 202. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
2 **UCTS DURING INITIAL PERIOD.**

3 Section 1847A(c)(4) of the Social Security Act (42
4 U.S.C. 1395w-3a(c)(4)) is amended—

5 (1) in each of subparagraphs (A) and (B), by
6 redesignating clauses (i) and (ii) as subclauses (I)
7 and (II), respectively, and moving such subclauses 2
8 ems to the right;

9 (2) by redesignating subparagraphs (A) and
10 (B) as clauses (i) and (ii) and moving such clauses
11 2 ems to the right;

12 (3) by striking “UNAVAILABLE.—In the case”
13 and inserting “UNAVAILABLE.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), in the case”; and

16 (4) by adding at the end the following new sub-
17 paragraph:

18 “(B) LIMITATION ON PAYMENT AMOUNT
19 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
20 ING INITIAL PERIOD.—In the case of a bio-
21 similar biological product furnished on or after
22 July 1, 2023, in lieu of applying subparagraph
23 (A) during the initial period described in such
24 subparagraph with respect to the biosimilar bio-
25 logical product, the amount payable under this

1 section for the biosimilar biological product is
2 the lesser of the following:

3 “(i) The amount determined under
4 clause (ii) of such subparagraph for the
5 biosimilar biological product.

6 “(ii) The amount determined under
7 subsection (b)(1)(B) for the reference bio-
8 logical product.”.

9 **SEC. 203. TEMPORARY INCREASE IN MEDICARE PART B**
10 **PAYMENT FOR BIOSIMILAR BIOLOGICAL**
11 **PRODUCTS.**

12 Section 1847A(b)(8) of the Social Security Act (42
13 U.S.C. 1395w-3a(b)(8)) is amended—

14 (1) by redesignating subparagraphs (A) and
15 (B) as clauses (i) and (ii), respectively, and indent-
16 ing appropriately;

17 (2) by striking “PRODUCT.—The amount” and
18 inserting the following: “PRODUCT.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (B), the amount”; and

21 (3) by adding at the end the following new sub-
22 paragraph:

23 “(B) TEMPORARY PAYMENT INCREASE FOR
24 BIOSIMILAR BIOLOGICAL PRODUCTS.—

1 “(i) IN GENERAL.—Beginning Janu-
2 ary 1, 2023, in the case of a biosimilar bio-
3 logical product described in paragraph
4 (1)(C) that is furnished during the applica-
5 ble 5-year period for such product, the
6 amount specified in this paragraph for
7 such product is an amount equal to the
8 lesser of the following:

9 “(I) The amount specified in sub-
10 paragraph (A) for such product if
11 clause (ii) of such subparagraph was
12 applied by substituting ‘8 percent’ for
13 ‘6 percent’.

14 “(II) The amount determined
15 under subsection (b)(1)(B) for the
16 reference biological product.

17 “(ii) APPLICABLE 5-YEAR PERIOD.—
18 For purposes of clause (i), the applicable
19 5-year period for a biosimilar biological
20 product is—

21 “(I) in the case of such a product
22 for which payment was made under
23 this paragraph as of December 31,
24 2012, the 5-year period beginning on
25 January 1, 2023; and

1 “(II) in the case of such a prod-
2 uct that is not described in subclause
3 (I), the 5-year period beginning on the
4 first day of the first calendar quarter
5 in which payment was made for such
6 product under this paragraph.”.

7 **SEC. 204. MEDICARE PART B REBATE BY MANUFACTURERS.**

8 (a) IN GENERAL.—Section 1834 of the Social Secu-
9 rity Act (42 U.S.C. 1395m) is amended by adding at the
10 end the following new subsection:

11 “(x) REBATE BY MANUFACTURERS FOR SINGLE
12 SOURCE DRUGS WITH PRICES INCREASING FASTER
13 THAN INFLATION.—

14 “(1) REQUIREMENTS.—

15 “(A) SECRETARIAL PROVISION OF INFOR-
16 MATION.—Not later than 6 months after the
17 end of each calendar quarter beginning on or
18 after July 1, 2024, the Secretary shall, for each
19 part B rebatable drug, report to each manufac-
20 turer of such part B rebatable drug the fol-
21 lowing for such calendar quarter:

22 “(i) Information on the total number
23 of units of the billing and payment code
24 described in subparagraph (A)(i) of para-

1 graph (3) with respect to such drug and
2 calendar quarter.

3 “(ii) Information on the amount (if
4 any) of the excess average sales price in-
5 crease described in subparagraph (A)(ii) of
6 such paragraph for such drug and calendar
7 quarter.

8 “(iii) The rebate amount specified
9 under such paragraph for such part B
10 rebatable drug and calendar quarter.

11 “(B) MANUFACTURER REQUIREMENT.—
12 For each calendar quarter beginning on or after
13 July 1, 2024, the manufacturer of a part B
14 rebatable drug shall, for such drug, not later
15 than 30 days after the date of receipt from the
16 Secretary of the information described in sub-
17 paragraph (A) for such calendar quarter, pro-
18 vide to the Secretary a rebate that is equal to
19 the amount specified in paragraph (3) for such
20 drug for such calendar quarter.

21 “(2) PART B REBATABLE DRUG DEFINED.—

22 “(A) IN GENERAL.—In this subsection, the
23 term ‘part B rebatable drug’ means a single
24 source drug or biological (as defined in sub-
25 paragraph (D) of section 1847A(e)(6)), includ-

1 ing a biosimilar biological product (as defined
2 in subparagraph (H) of such section), paid for
3 under this part, except such term shall not in-
4 clude such a drug or biological—

5 “(i) if the average total allowed
6 charges for a year per individual that uses
7 such a drug or biological, as determined by
8 the Secretary, are less than, subject to
9 subparagraph (B), \$100; or

10 “(ii) that is a vaccine described in
11 subparagraph (A) or (B) of section
12 1861(s)(10).

13 “(B) INCREASE.—The dollar amount ap-
14 plied under subparagraph (A)(i)—

15 “(i) for 2025, shall be the dollar
16 amount specified under such subparagraph
17 for 2024, increased by the percentage in-
18 crease in the consumer price index for all
19 urban consumers (United States city aver-
20 age) for the 12 month period ending with
21 June of the previous year; and

22 “(ii) for a subsequent year, shall be
23 the dollar amount specified in this clause
24 (or clause (i)) for the previous year, in-
25 creased by the percentage increase in the

1 consumer price index for all urban con-
2 sumers (United States city average) for
3 the 12 month period ending with June of
4 the previous year.

5 Any dollar amount specified under this sub-
6 paragraph that is not a multiple of \$10 shall be
7 rounded to the nearest multiple of \$10.

8 “(3) REBATE AMOUNT.—

9 “(A) IN GENERAL.—For purposes of para-
10 graph (1), the amount specified in this para-
11 graph for a part B rebatable drug assigned to
12 a billing and payment code for a calendar quar-
13 ter is, subject to paragraph (4), the amount
14 equal to the product of—

15 “(i) subject to subparagraphs (B) and
16 (G), the total number of units of the bill-
17 ing and payment code for such part B
18 rebatable drug furnished under this part
19 during the calendar quarter; and

20 “(ii) the amount (if any) by which—

21 “(I) the payment amount under
22 subparagraph (B) or (C) of section
23 1847A(b)(1), as applicable, for such
24 part B rebatable drug during the cal-
25 endar quarter; exceeds

1 “(II) the inflation-adjusted pay-
2 ment amount determined under sub-
3 paragraph (C) for such part B
4 rebtable drug during the calendar
5 quarter.

6 “(B) EXCLUDED UNITS.—For purposes of
7 subparagraph (A)(i), the total number of units
8 of the billing and payment code for each part
9 B rebtable drug furnished during a calendar
10 quarter shall not include—

11 “(i) units packaged into the payment
12 for a procedure or service under section
13 1833(t) or under section 1833(i) (instead
14 of separately payable under such respective
15 section);

16 “(ii) units included under the single
17 payment system for renal dialysis services
18 under section 1881(b)(14); or

19 “(iii) units of a part B rebtable drug
20 of a manufacturer furnished to an indi-
21 vidual, if such manufacturer, with respect
22 to the furnishing of such units of such
23 drug, provides for discounts under section
24 340B of the Public Health Service Act or
25 for rebates under section 1927.

1 “(C) DETERMINATION OF INFLATION-AD-
2 JUSTED PAYMENT AMOUNT.—The inflation-ad-
3 justed payment amount determined under this
4 subparagraph for a part B rebatable drug for
5 a calendar quarter is—

6 “(i) the payment amount for the bill-
7 ing and payment code for such drug in the
8 payment amount benchmark quarter (as
9 defined in subparagraph (D)); increased by

10 “(ii) the percentage by which the re-
11 bate period CPI–U (as defined in subpara-
12 graph (F)) for the calendar quarter ex-
13 ceeds the benchmark period CPI–U (as de-
14 fined in subparagraph (E)).

15 “(D) PROSPECTIVE PAYMENT AMOUNT
16 BENCHMARK QUARTER.—The term ‘prospective
17 payment amount benchmark quarter’ means the
18 calendar quarter beginning January 1, 2016.

19 “(E) BENCHMARK PERIOD CPI–U.—The
20 term ‘benchmark period CPI–U’ means the con-
21 sumer price index for all urban consumers
22 (United States city average) for July 2015.

23 “(F) REBATE PERIOD CPI–U.—The term
24 ‘rebate period CPI–U’ means, with respect to a
25 calendar quarter described in subparagraph

1 (C), the greater of the benchmark period CPI–
2 U and the consumer price index for all urban
3 consumers (United States city average) for the
4 first month of the calendar quarter that is two
5 calendar quarters prior to such described cal-
6 endar quarter.

7 “(G) COUNTING UNITS.—

8 “(i) CUT-OFF PERIOD TO COUNT
9 UNITS.—For purposes of subparagraph
10 (A)(i), subject to clause (ii), to count the
11 total number of billing units for a part B
12 rebatable drug for a quarter, the Secretary
13 may use a cut-off period in order to ex-
14 clude from such total number of billing
15 units for such quarter claims for services
16 furnished during such quarter that were
17 not processed at an appropriate time prior
18 to the end of the cut-off period.

19 “(ii) COUNTING UNITS FOR CLAIMS
20 PROCESSED AFTER CUT-OFF PERIOD.—If
21 the Secretary uses a cut-off period pursu-
22 ant to clause (i), in the case of units of a
23 part B rebatable drug furnished during a
24 quarter but pursuant to application of such
25 cut-off period excluded for purposes of sub-

1 paragraph (A)(i) from the total number of
2 billing units for the drug for such quarter,
3 the Secretary shall count such units of
4 such drug so furnished in the total number
5 of billing units for such drug for a subse-
6 quent quarter, as the Secretary determines
7 appropriate.

8 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
9 AND EXEMPTION.—

10 “(A) SUBSEQUENTLY APPROVED DRUGS.—
11 Subject to subparagraph (B), in the case of a
12 part B rebatable drug first approved or licensed
13 by the Food and Drug Administration after
14 July 1, 2015, clause (i) of paragraph (3)(C)
15 shall be applied as if the term ‘payment amount
16 benchmark quarter’ were defined under para-
17 graph (3)(D) as the third full calendar quarter
18 after the day on which the drug was first mar-
19 keted and clause (ii) of paragraph (3)(C) shall
20 be applied as if the term ‘benchmark period
21 CPI-U’ were defined under paragraph (3)(E)
22 as if the reference to ‘July 2015’ under such
23 paragraph were a reference to ‘the first month
24 of the first full calendar quarter after the day
25 on which the drug was first marketed’.

1 “(B) TIMELINE FOR PROVISION OF RE-
2 BATES FOR SUBSEQUENTLY APPROVED
3 DRUGS.—In the case of a part B rebatable drug
4 first approved or licensed by the Food and
5 Drug Administration after July 1, 2015, para-
6 graph (1)(B) shall be applied as if the reference
7 to ‘July 1, 2024’ under such paragraph were a
8 reference to the later of the 6th full calendar
9 quarter after the day on which the drug was
10 first marketed or July 1, 2024.

11 “(C) EXEMPTION FOR SHORTAGES.—The
12 Secretary may reduce or waive the rebate
13 amount under paragraph (1)(B) with respect to
14 a part B rebatable drug that is described as
15 currently in shortage on the shortage list in ef-
16 fect under section 506E of the Federal Food,
17 Drug, and Cosmetic Act or in the case of other
18 exigent circumstances, as determined by the
19 Secretary.

20 “(D) SELECTED DRUGS.—In the case of a
21 part B rebatable drug that is a selected drug
22 (as defined in section 1192(e)) for a price appli-
23 cability period (as defined in section
24 1191(b)(2))—

1 “(i) for calendar quarters during such
2 period for which a maximum fair price (as
3 defined in section 1191(c)(2)) for such
4 drug has been determined and is applied
5 under part E of title XI, the rebate
6 amount under paragraph (1)(B) shall be
7 waived; and

8 “(ii) in the case such drug is deter-
9 mined (pursuant to such section 1192(e))
10 to no longer be a selected drug, for each
11 applicable year beginning after the price
12 applicability period with respect to such
13 drug, clause (i) of paragraph (3)(C) shall
14 be applied as if the term ‘payment amount
15 benchmark quarter’ were defined under
16 paragraph (3)(D) as the calendar quarter
17 beginning January 1 of the last year be-
18 ginning during such price applicability pe-
19 riod with respect to such selected drug and
20 clause (ii) of paragraph (3)(C) shall be ap-
21 plied as if the term ‘benchmark period
22 CPI-U’ were defined under paragraph
23 (3)(E) as if the reference to ‘July 2015’
24 under such paragraph were a reference to

1 the July of the year preceding such last
2 year.

3 “(5) APPLICATION TO BENEFICIARY COINSUR-
4 ANCE.—In the case of a part B rebatable drug, if
5 the payment amount for a quarter exceeds the infla-
6 tion adjusted payment for such quarter—

7 “(A) in computing the amount of any coin-
8 surance applicable under this title to an indi-
9 vidual with respect to such drug, the computa-
10 tion of such coinsurance shall be based on the
11 inflation-adjusted payment amount determined
12 under paragraph (3)(C) for such part B
13 rebatable drug; and

14 “(B) the amount of such coinsurance is
15 equal to 20 percent of such inflation-adjusted
16 payment amount so determined.

17 “(6) REBATE DEPOSITS.—Amounts paid as re-
18 bates under paragraph (1)(B) shall be deposited into
19 the Federal Supplementary Medical Insurance Trust
20 Fund established under section 1841.

21 “(7) CIVIL MONEY PENALTY.—If a manufac-
22 turer of a part B rebatable drug has failed to com-
23 ply with the requirements under paragraph (1)(B)
24 for such drug for a calendar quarter, the manufac-
25 turer shall be subject to, in accordance with a proc-

1 ess established by the Secretary pursuant to regula-
2 tions, a civil money penalty in an amount equal to
3 at least 125 percent of the amount specified in para-
4 graph (3) for such drug for such calendar quarter.
5 The provisions of section 1128A (other than sub-
6 sections (a) (with respect to amounts of penalties or
7 additional assessments) and (b)) shall apply to a
8 civil money penalty under this paragraph in the
9 same manner as such provisions apply to a penalty
10 or proceeding under section 1128A(a).

11 “(8) STUDY AND REPORT.—

12 “(A) STUDY.—The Secretary shall conduct
13 a study of the feasibility of and operational
14 issues involved with the following:

15 “(i) Including multiple source drugs
16 (as defined in section 1847A(c)(6)(C)) in
17 the rebate system under this subsection.

18 “(ii) Including drugs and biologicals
19 paid for under MA plans under part C in
20 the rebate system under this subsection.

21 “(iii) Including drugs excluded under
22 paragraph (2)(A) and units of the billing
23 and payment code of the drugs excluded
24 under paragraph (3)(B) in the rebate sys-
25 tem under this subsection.

1 “(B) REPORT.—Not later than 3 years
2 after the date of the enactment of this sub-
3 section, the Secretary shall submit to Congress
4 a report on the study conducted under subpara-
5 graph (A).

6 “(9) APPLICATION TO MULTIPLE SOURCE
7 DRUGS.—The Secretary may, based on the report
8 submitted under paragraph (8) and pursuant to
9 rulemaking, apply the provisions of this subsection
10 to multiple source drugs (as defined in section
11 1847A(c)(6)(C)), including, for purposes of deter-
12 mining the rebate amount under paragraph (3), by
13 calculating manufacturer-specific average sales
14 prices for the benchmark period and the rebate pe-
15 riod.”.

16 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
17 1833 of the Social Security Act (42 U.S.C. 1395l) is
18 amended—

19 (1) in subsection (a)—

20 (A) in paragraph (1)—

21 (i) in subparagraph (S), by striking
22 “with respect to” and inserting “subject to
23 subparagraph (DD), with respect to”;

24 (ii) by striking “and (CC)” and in-
25 serting “(CC)”; and

1 (iii) by inserting before the semicolon
2 at the end the following: “, and (DD) with
3 respect to a part B rebatable drug (as de-
4 fined in paragraph (2) of section 1834(x))
5 for which the payment amount for a cal-
6 endar quarter under paragraph
7 (3)(A)(ii)(I) of such section for such quar-
8 ter exceeds the inflation-adjusted payment
9 under paragraph (3)(A)(ii)(II) of such sec-
10 tion for such quarter, the amounts paid
11 shall be the difference between (i) the pay-
12 ment amount under paragraph
13 (3)(A)(ii)(I) of such section for such drug,
14 and (ii) 20 percent of the inflation-ad-
15 justed payment amount under paragraph
16 (3)(A)(ii)(II) of such section for such
17 drug”;

18 (B) by adding at the end of the flush left
19 matter following paragraph (9), the following:

20 “For purposes of applying paragraph (1)(DD), sub-
21 sections (i)(9) and (t)(8)(F), and section 1834(x)(5), the
22 Secretary shall make such estimates and use such data
23 as the Secretary determines appropriate, and notwith-
24 standing any other provision of law, may do so by program
25 instruction or otherwise.”;

1 (2) in subsection (i), by adding at the end the
2 following new paragraph:

3 “(9) In the case of a part B rebatable drug (as
4 defined in paragraph (2) of section 1834(x)) for
5 which payment under this subsection is not pack-
6 aged into a payment for a covered OPD service (as
7 defined in subsection (t)(1)(B)) (or group of serv-
8 ices) furnished on or after July 1, 2024, under the
9 system under this subsection, in lieu of calculation
10 of coinsurance and the amount of payment otherwise
11 applicable under this subsection, the provisions of
12 section 1834(x)(5), paragraph (1)(DD) of subsection
13 (a), and the flush left matter following paragraph
14 (9) of subsection (a), shall, as determined appro-
15 priate by the Secretary, apply under this subsection
16 in the same manner as such provisions of section
17 1834(x)(5) and subsection (a) apply under such sec-
18 tion and subsection.”; and

19 (3) in subsection (t)(8), by adding at the end
20 the following new subparagraph:

21 “(F) PART B REBATABLE DRUGS.—In the
22 case of a part B rebatable drug (as defined in
23 paragraph (2) of section 1834(x)) for which
24 payment under this part is not packaged into a
25 payment for a service furnished on or after July

1 1, 2024, under the system under this sub-
2 section, in lieu of calculation of coinsurance and
3 the amount of payment otherwise applicable
4 under this subsection, the provisions of section
5 1834(x)(5), paragraph (1)(DD) of subsection
6 (a), and the flush left matter following para-
7 graph (9) of subsection (a), shall, as determined
8 appropriate by the Secretary, apply under this
9 subsection in the same manner as such provi-
10 sions of section 1834(x)(5) and subsection (a)
11 apply under such section and subsection.”.

12 (c) CONFORMING AMENDMENTS.—

13 (1) TO PART B ASP CALCULATION.—Section
14 1847A(c)(3) of the Social Security Act (42 U.S.C.
15 1395w–3a(c)(3)) is amended by inserting “or section
16 1834(x)” after “section 1927”.

17 (2) EXCLUDING PARTS B DRUG INFLATION RE-
18 BATE FROM BEST PRICE.—Section
19 1927(e)(1)(C)(ii)(I) of the Social Security Act (42
20 U.S.C. 1396r–8(e)(1)(C)(ii)(I)) is amended by in-
21 serting “or section 1834(x)” after “this section”.

22 (3) COORDINATION WITH MEDICAID REBATE IN-
23 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
24 of the Social Security Act (42 U.S.C. 1396r–
25 8(b)(3)(D)(i)) is amended by striking “or to carry

1 out section 1847B” and inserting “to carry out sec-
2 tion 1847B or section 1834(x)”.

3 **SEC. 205. ESTABLISHMENT OF MAXIMUM ADD-ON PAYMENT**
4 **FOR DRUGS AND BIOLOGICALS.**

5 (a) IN GENERAL.—Section 1847A of the Social Secu-
6 rity Act (42 U.S.C. 1395w–3a) is amended—

7 (1) in subsection (b)—

8 (A) in paragraph (1), in the matter pre-
9 ceeding subparagraph (A), by striking “para-
10 graph (7)” and inserting “paragraphs (7) and
11 (9)”; and

12 (B) by adding at the end the following new
13 paragraph:

14 “(9) MAXIMUM ADD-ON PAYMENT AMOUNT.—

15 “(A) IN GENERAL.—In determining the
16 payment amount under the provisions of sub-
17 paragraph (A), (B), or (C) of paragraph (1) of
18 this subsection, subsection (c)(4)(A)(ii), or sub-
19 section (d)(3)(C) for a drug or biological fur-
20 nished on or after January 1, 2024, if the ap-
21 plicable add-on payment (as defined in subpara-
22 graph (B)) for each drug or biological on a
23 claim for a date of service exceeds the max-
24 imum add-on payment amount specified under
25 subparagraph (C) for the drug or biological,

1 then the payment amount otherwise determined
2 for the drug or biological under those provi-
3 sions, as applicable, shall be reduced by the
4 amount of such excess.

5 “(B) APPLICABLE ADD-ON PAYMENT DE-
6 FINED.—In this paragraph, the term ‘applicable
7 add-on payment’ means the following amounts,
8 determined without regard to the application of
9 subparagraph (A):

10 “(i) In the case of a multiple source
11 drug, an amount equal to the difference
12 between—

13 “(I) the amount that would oth-
14 erwise be applied under paragraph
15 (1)(A); and

16 “(II) the amount that would be
17 applied under such paragraph if ‘100
18 percent’ were substituted for ‘106 per-
19 cent’.

20 “(ii) In the case of a single source
21 drug or biological, an amount equal to the
22 difference between—

23 “(I) the amount that would oth-
24 erwise be applied under paragraph
25 (1)(B); and

1 “(II) the amount that would be
2 applied under such paragraph if ‘100
3 percent’ were substituted for ‘106 per-
4 cent’.

5 “(iii) In the case of a biosimilar bio-
6 logical product, the amount otherwise de-
7 termined under paragraph (8)(B).

8 “(iv) In the case of a drug or biologi-
9 cal during the initial period described in
10 subsection (c)(4)(A), an amount equal to
11 the difference between—

12 “(I) the amount that would oth-
13 erwise be applied under subsection
14 (c)(4)(A)(ii); and

15 “(II) the amount that would be
16 applied under such subsection if ‘100
17 percent’ were substituted, as applica-
18 ble, for—

19 “(aa) ‘103 percent’ in sub-
20 clause (I) of such subsection; or

21 “(bb) any percent in excess
22 of 100 percent applied under
23 subclause (II) of such subsection.

24 “(v) In the case of a drug or biologi-
25 cal to which subsection (d)(3)(C) applies,

1 an amount equal to the difference be-
2 tween—

3 “(I) the amount that would oth-
4 erwise be applied under such sub-
5 section; and

6 “(II) the amount that would be
7 applied under such subsection if ‘100
8 percent’ were substituted, as applica-
9 ble, for—

10 “(aa) any percent in excess
11 of 100 percent applied under
12 clause (i) of such subsection; or

13 “(bb) ‘103 percent’ in clause
14 (ii) of such subsection.

15 “(C) MAXIMUM ADD-ON PAYMENT AMOUNT
16 SPECIFIED.—For purposes of subparagraph
17 (A), the maximum add-on payment amount
18 specified in this subparagraph is—

19 “(i) for each of 2024 through 2031,
20 \$1,000; and

21 “(ii) for a subsequent year, the
22 amount specified in this subparagraph for
23 the preceding year increased by the per-
24 centage increase in the consumer price
25 index for all urban consumers (all items;

1 United States city average) for the 12-
2 month period ending with June of the pre-
3 vious year.

4 Any amount determined under this subpara-
5 graph that is not a multiple of \$10 shall be
6 rounded to the nearest multiple of \$10.”; and
7 (2) in subsection (c)(4)(A)(ii), by striking “in
8 the case” and inserting “subject to subsection
9 (b)(9), in the case”.

10 (b) CONFORMING AMENDMENTS RELATING TO SEPA-
11 RATELY PAYABLE DRUGS.—

12 (1) OPPS.—Section 1833(t)(14) of the Social
13 Security Act (42 U.S.C. 1395l(t)(14)) is amended—

14 (A) in subparagraph (A)(iii)(II), by insert-
15 ing “, subject to subparagraph (I)” after “are
16 not available”; and

17 (B) by adding at the end the following new
18 subparagraph:

19 “(I) APPLICATION OF MAXIMUM ADD-ON
20 PAYMENT FOR SEPARATELY PAYABLE DRUGS
21 AND BIOLOGICALS.—In establishing the amount
22 of payment under subparagraph (A) for a speci-
23 fied covered outpatient drug that is furnished
24 as part of a covered OPD service (or group of
25 services) on or after January 1, 2024, if such

1 payment is determined based on the average
2 price for the year established under section
3 1847A pursuant to clause (iii)(II) of such sub-
4 paragraph, the provisions of subsection (b)(9)
5 of section 1847A shall apply to the amount of
6 payment so established in the same manner as
7 such provisions apply to the amount of payment
8 under section 1847A.”.

9 (2) ASC.—Section 1833(i)(2)(D) of the Social
10 Security Act (42 U.S.C. 1395l(i)(2)(D)) is amend-
11 ed—

12 (A) by moving clause (v) 6 ems to the left;

13 (B) by redesignating clause (vi) as clause
14 (vii); and

15 (C) by inserting after clause (v) the fol-
16 lowing new clause:

17 “(vi) If there is a separate payment under the system
18 described in clause (i) for a drug or biological furnished
19 on or after January 1, 2024, the provisions of subsection
20 (t)(14)(I) shall apply to the establishment of the amount
21 of payment for the drug or biological under such system
22 in the same manner in which such provisions apply to the
23 establishment of the amount of payment under subsection
24 (t)(14)(A).”.

1 **SEC. 206. GAO STUDY AND REPORT ON AVERAGE SALES**

2 **PRICE.**

3 (a) STUDY.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States (in this section referred to as the
6 “Comptroller General”) shall conduct a study on
7 spending for applicable drugs under part B of title
8 XVIII of the Social Security Act.

9 (2) APPLICABLE DRUGS DEFINED.—In this sec-
10 tion, the term “applicable drugs” means drugs and
11 biologicals—

12 (A) for which reimbursement under such
13 part B is based on the average sales price of
14 the drug or biological; and

15 (B) that account for the largest percentage
16 of total spending on drugs and biologicals under
17 such part B (as determined by the Comptroller
18 General, but in no case less than 25 drugs or
19 biologicals).

20 (3) REQUIREMENTS.—The study under para-
21 graph (1) shall include an analysis of the following:

22 (A) The extent to which each applicable
23 drug is paid for—

24 (i) under such part B for Medicare
25 beneficiaries; or

1 (ii) by private payers in the commer-
2 cial market.

3 (B) Any change in Medicare spending or
4 Medicare beneficiary cost-sharing that would
5 occur if the average sales price of an applicable
6 drug was based solely on payments by private
7 payers in the commercial market.

8 (C) The extent to which drug manufactur-
9 ers provide rebates, discounts, or other price
10 concessions to private payers in the commercial
11 market for applicable drugs, which the manu-
12 facturer includes in its average sales price cal-
13 culation, for—

14 (i) formulary placement;

15 (ii) utilization management consider-
16 ations; or

17 (iii) other purposes.

18 (D) Barriers to drug manufacturers pro-
19 viding such price concessions for applicable
20 drugs.

21 (E) Other areas determined appropriate by
22 the Comptroller General.

23 (b) REPORT.—Not later than 2 years after the date
24 of the enactment of this Act, the Comptroller General shall
25 submit to Congress a report on the study conducted under

1 subsection (a), together with recommendations for such
2 legislation and administrative action as the Secretary de-
3 termines appropriate.

4 **SEC. 207. AUTHORITY TO USE ALTERNATIVE PAYMENT FOR**
5 **DRUGS AND BIOLOGICALS TO PREVENT PO-**
6 **TENTIAL DRUG SHORTAGES.**

7 (a) IN GENERAL.—Section 1847A(e) of the Social
8 Security Act (42 U.S.C. 1395w–3a(e)) is amended—

9 (1) by striking “PAYMENT IN RESPONSE TO
10 PUBLIC HEALTH EMERGENCY.—In the case” and
11 inserting “PAYMENTS.—

12 “(1) IN RESPONSE TO PUBLIC HEALTH EMER-
13 GENCY.—In the case”; and

14 (2) by adding at the end the following new
15 paragraph:

16 “(2) PREVENTING POTENTIAL DRUG SHORT-
17 AGES.—

18 “(A) IN GENERAL.—In the case of a drug
19 or biological that the Secretary determines is
20 described in subparagraph (B) for one or more
21 quarters beginning on or after January 1,
22 2024, the Secretary may use wholesale acquisi-
23 tion cost (or other reasonable measure of a
24 drug or biological price) instead of the manu-
25 facturer’s average sales price for such quarters

1 and for subsequent quarters until the end of
2 the quarter in which such drug or biological is
3 removed from the drug shortage list under sec-
4 tion 506E of the Federal Food, Drug, and Cos-
5 metic Act, or in the case of a drug or biological
6 described in subparagraph (B)(ii), the date on
7 which the Secretary determines that the total
8 manufacturing capacity or the total number of
9 manufacturers of such drug or biological is suf-
10 ficient to mitigate a potential shortage of the
11 drug or biological.

12 “(B) DRUG OR BIOLOGICAL DESCRIBED.—
13 For purposes of subparagraph (A), a drug or
14 biological described in this subparagraph is a
15 drug or biological—

16 “(i) that is listed on the drug shortage
17 list maintained by the Food and Drug Ad-
18 ministration pursuant to section 506E of
19 the Federal Food, Drug, and Cosmetic
20 Act, and with respect to which any manu-
21 facturer of such drug or biological notifies
22 the Secretary of a permanent discontinu-
23 ance or an interruption that is likely to
24 lead to a meaningful disruption in the

1 manufacturer's supply of that drug pursu-
2 ant to section 506C(a) of such Act; or

3 “(ii) that—

4 “(I) is described in section
5 506C(a) of such Act;

6 “(II) was listed on the drug
7 shortage list maintained by the Food
8 and Drug Administration pursuant to
9 section 506E of such Act within the
10 preceding 5 years; and

11 “(III) for which the total manu-
12 facturing capacity of all manufactur-
13 ers with an approved application for
14 such drug or biological that is cur-
15 rently marketed or total number of
16 manufacturers with an approved ap-
17 plication for such drug or biological
18 that is currently marketed declines
19 during a 6-month period, as deter-
20 mined by the Secretary.

21 “(C) PROVISION OF ADDITIONAL INFORMA-
22 TION.—For each quarter in which the amount
23 of payment for a drug or biological described in
24 subparagraph (B) pursuant to subparagraph
25 (A) exceeds the amount of payment for the

1 drug or biological otherwise applicable under
2 this section, each manufacturer of such drug or
3 biological shall provide to the Secretary infor-
4 mation related to the potential cause or causes
5 of the shortage and the expected duration of
6 the shortage with respect to such drug.”.

7 (b) TRACKING SHORTAGE DRUGS THROUGH
8 CLAIMS.—The Secretary of Health and Human Services
9 (referred to in this section as the “Secretary”) shall estab-
10 lish a mechanism (such as a modifier) for purposes of
11 tracking utilization under title XVIII of the Social Secu-
12 rity Act (42 U.S.C. 1395 et seq.) of drugs and biologicals
13 listed on the drug shortage list maintained by the Food
14 and Drug Administration pursuant to section 506E of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

16 (c) HHS REPORT AND RECOMMENDATIONS.—

17 (1) IN GENERAL.—Not later than July 1, 2024,
18 the Secretary shall submit to Congress a report on
19 shortages of drugs within the Medicare program
20 under title XVIII of the Social Security Act (42
21 U.S.C. 1395 et seq.). The report shall include—

22 (A) an analysis of—

23 (i) the effect of drug shortages on
24 Medicare beneficiary access, quality, safe-
25 ty, and out-of-pocket costs;

1 (ii) the effect of drug shortages on
2 health providers, including hospitals and
3 physicians, across the Medicare program;

4 (iii) the current role of the Centers for
5 Medicare & Medicaid Services (CMS) in
6 addressing drug shortages, including
7 CMS's working relationship and commu-
8 nication with other Federal agencies and
9 stakeholders;

10 (iv) the role of all actors in the drug
11 supply chain (including drug manufactur-
12 ers, distributors, wholesalers, secondary
13 wholesalers, group purchasing organiza-
14 tions, hospitals, and physicians) on drug
15 shortages within the Medicare program;
16 and

17 (v) payment structures and incentives
18 under parts A, B, C, and D of the Medi-
19 care program and their effect, if any, on
20 drug shortages; and

21 (B) relevant findings and recommendations
22 to Congress.

23 (2) PUBLIC AVAILABILITY.—The report under
24 this subsection shall be made available to the public.

1 (3) CONSULTATION.—The Secretary shall con-
2 sult with the drug shortage task force authorized
3 under section 506D(a)(1)(A) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 356d(a)(1)(A))
5 in preparing the report under this subsection, as ap-
6 propriate.

7 **SEC. 208. CHANGE IN DEFINITION OF STRENGTH FOR THE**
8 **PURPOSES OF DETERMINING INTERCHANGE-**
9 **ABILITY OF BIOLOGICAL AND BIOSIMILAR**
10 **PRODUCTS.**

11 (a) Section 351(i) of the Public Health Service Act
12 is amended by inserting the following after paragraph (4):

13 “(5) The term “strength,” in reference to a bio-
14 logical product intended for administration by injec-
15 tion, means the total content of drug substance in
16 the dosage form without regard to the concentration
17 of drug substance or total volume of the biological
18 product.’”.

19 (b) Section 351(k)(7)(C)(ii)(I) of the Public Health
20 Service Act is amended by inserting “concentration,” after
21 “delivery device,”.

Subtitle B—Part D

1

2 SEC. 209. MEDICARE PART D MODERNIZATION REDESIGN.

3 (a) BENEFIT STRUCTURE REDESIGN.—Section
4 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
5 102(b)) is amended—

6 (1) in paragraph (2)—

7 (A) in subparagraph (A), in the matter
8 preceding clause (i), by inserting “for a year
9 preceding 2024 and for costs above the annual
10 deductible specified in paragraph (1) and up to
11 the annual out-of-pocket threshold specified in
12 paragraph (4)(B) for 2024 and each subsequent
13 year” after “paragraph (3)”;

14 (B) in subparagraph (C)—

15 (i) in clause (i), in the matter pre-
16 ceding subclause (I), by inserting “for a
17 year preceding 2024,” after “paragraph
18 (4),”; and

19 (ii) in clause (ii)(III), by striking
20 “and each subsequent year” and inserting
21 “, 2021, 2022, and 2023”; and

22 (C) in subparagraph (D)—

23 (i) in clause (i)—

24 (I) in the matter preceding sub-
25 clause (I), by inserting “for a year

1 preceding 2024,” after “paragraph
2 (4),”; and

3 (II) in subclause (I)(bb), by
4 striking “a year after 2018” and in-
5 sserting “each of years 2018 through
6 2023”; and

7 (ii) in clause (ii)(V), by striking
8 “2019 and each subsequent year” and in-
9 sserting “each of years through 2023”;

10 (2) in paragraph (3)(A)—

11 (A) in the matter preceding clause (i), by
12 inserting “for a year preceding 2024,” after
13 “and (4),”; and

14 (B) in clause (ii), by striking “for a subse-
15 quent year” and inserting “for each of years
16 2007 through 2023”;

17 (3) in paragraph (4)—

18 (A) in subparagraph (A)—

19 (i) in clause (i)—

20 (I) by redesignating subclauses
21 (I) and (II) as items (aa) and (bb),
22 respectively, and indenting appro-
23 priately;

24 (II) in the matter preceding item
25 (aa), as redesignated by subclause (I),

1 by striking “is equal to the greater
2 of—” and inserting “is equal to—

3 “(I) for a year preceding 2024,
4 the greater of—”;

5 (III) by striking the period at the
6 end of item (bb), as redesignated by
7 subclause (I), and inserting “; and”;
8 and

9 (IV) by adding at the end the fol-
10 lowing:

11 “(II) for and each succeeding
12 year, \$0.”; and

13 (ii) in clause (ii)—

14 (I) by striking “clause (i)(I)” and
15 inserting “clause (i)(I)(aa)”;

16 (II) by adding at the end the fol-
17 lowing new sentence: “The Secretary
18 shall continue to calculate the dollar
19 amounts specified in clause (i)(I)(aa),
20 including with the adjustment under
21 this clause, after 2023 for purposes of
22 section 1860D–14(a)(1)(D)(iii).”;

23 (B) in subparagraph (B)—

24 (i) in clause (i)—

1 (I) in subclause (V), by striking
2 “or” at the end;

3 (II) in subclause (VI)—

4 (aa) by striking “for a sub-
5 sequent year” and inserting “for
6 2021, 2022, and 2023”; and

7 (bb) by striking the period
8 at the end and inserting a semi-
9 colon; and

10 (III) by adding at the end the
11 following new subclauses:

12 “(VII) for 2024, is equal to—

13 “(aa) \$3,100 for bene-
14 ficiaries determined to have in-
15 come that is over 400 percent of
16 the federal poverty line applicable
17 to a family of the size involved;

18 “(bb) \$1,800 for bene-
19 ficiaries determined to have in-
20 come that is between 300 to 400
21 percent of the federal poverty line
22 applicable to a family of the size
23 involved; or

24 “(cc) \$1,200 for bene-
25 ficiaries between determined to

1 have income that is below 300
2 percent of the federal poverty line
3 applicable to a family of the size
4 involved; or

5 “(VIII) for a subsequent year, is
6 equal to the amount specified in this
7 subparagraph for the previous year,
8 increased by the annual percentage in-
9 crease described in paragraph (6) for
10 the year involved.”; and

11 (ii) in clause (ii), by striking “clause
12 (i)(II)” and inserting “clause (i)”;

13 (C) in subparagraph (C)(i), by striking
14 “and for amounts” and inserting “and for a
15 year preceding 2024 for amounts”; and

16 (D) in subparagraph (E), by striking “In
17 applying” and inserting “For each of 2011
18 through 2023, in applying”.

19 (b) DECREASING REINSURANCE PAYMENT
20 AMOUNT.—Section 1860D–15(b) of the Social Security
21 Act (42 U.S.C. 1395w–115(b)) is amended—

22 (1) in paragraph (1)—

23 (A) by striking “equal to 80 percent” and
24 inserting “equal to—

1 “(A) for a year preceding 2024, 80 per-
2 cent”;

3 (B) in subparagraph (A), as added by
4 paragraph (1), by striking the period at the end
5 and inserting “; and”; and

6 (C) by adding at the end the following new
7 subparagraph:

8 “(B) for 2024 and each subsequent year,
9 the sum of—

10 “(i) an amount equal to the applicable
11 percentage specified in paragraph (5)(A) of
12 such allowable reinsurance costs attrib-
13 utable to that portion of gross prescription
14 drug costs as specified in paragraph (3) in-
15 curred in the coverage year after such indi-
16 vidual has incurred costs that exceed the
17 annual out-of-pocket threshold specified in
18 section 1860D–2(b)(4)(B) with respect to
19 applicable drugs (as defined in section
20 1860D–14B(g)(2)); and

21 “(ii) an amount equal to the applica-
22 ble percentage specified in paragraph
23 (5)(B) of allowable reinsurance costs at-
24 tributable to that portion of gross prescrip-
25 tion drug costs as specified in paragraph

1 (3) incurred in the coverage year after
2 such individual has incurred costs that ex-
3 ceed the annual out-of-pocket threshold
4 specified in section 1860D–2(b)(4)(B) with
5 respect to covered part D drugs that are
6 not applicable drugs (as so defined).”; and

7 (2) by adding at the end the following new
8 paragraph:

9 “(5) APPLICABLE PERCENTAGE SPECIFIED.—
10 For purposes of paragraph (1)(B), the applicable
11 percentage specified in this paragraph is—

12 “(A) with respect to applicable drugs (as
13 defined in section 1860D–14B(g)(2))—

14 “(i) for 2024, 60 percent;

15 “(ii) for 2025, 40 percent; and

16 “(iii) for 2026 and each subsequent
17 year, 20 percent; and

18 “(B) with respect to covered part D drugs
19 that are not applicable drugs (as so defined)—

20 “(i) for 2024, 80 percent;

21 “(ii) for 2025, 60 percent; and

22 “(iii) for 2026 and each subsequent
23 year, 40 percent.”.

24 (c) MANUFACTURER DISCOUNT PROGRAM DURING
25 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

1 (1) IN GENERAL.—Part D of title XVIII of the
2 Social Security Act is amended by inserting after
3 section 1860D–14A (42 U.S.C. 1495w–114) the fol-
4 lowing new section:

5 **“SEC. 1860D–14B. MANUFACTURER DISCOUNT PROGRAM.**

6 “(a) ESTABLISHMENT.—The Secretary shall estab-
7 lish a manufacturer discount program (in this section re-
8 ferred to as the ‘program’). Under the program, the Sec-
9 retary shall enter into agreements described in subsection
10 (b) with manufacturers and provide for the performance
11 of the duties described in subsection (c). The Secretary
12 shall establish a model agreement for use under the pro-
13 gram by not later than January 1, 2023, in consultation
14 with manufacturers, and allow for comment on such model
15 agreement.

16 “(b) TERMS OF AGREEMENT.—

17 “(1) IN GENERAL.—

18 “(A) AGREEMENT.—An agreement under
19 this section shall require the manufacturer to
20 provide applicable beneficiaries access to dis-
21 counted prices for applicable drugs of the man-
22 ufacturer that are dispensed on or after Janu-
23 ary 1, 2024.

24 “(B) PROVISION OF DISCOUNTED PRICES
25 AT THE POINT-OF-SALE.—The discounted prices

1 described in subparagraph (A) shall be provided
2 to the applicable beneficiary at the pharmacy or
3 by the mail order service at the point-of-sale of
4 an applicable drug.

5 “(2) PROVISION OF APPROPRIATE DATA.—Each
6 manufacturer with an agreement in effect under this
7 section shall collect and have available appropriate
8 data, as determined by the Secretary, to ensure that
9 it can demonstrate to the Secretary compliance with
10 the requirements under the program.

11 “(3) COMPLIANCE WITH REQUIREMENTS FOR
12 ADMINISTRATION OF PROGRAM.—Each manufac-
13 turer with an agreement in effect under this section
14 shall comply with requirements imposed by the Sec-
15 retary or a third party with a contract under sub-
16 section (d)(3), as applicable, for purposes of admin-
17 istering the program, including any determination
18 under subparagraph (A) of subsection (c)(1) or pro-
19 cedures established under such subsection (c)(1).

20 “(4) LENGTH OF AGREEMENT.—

21 “(A) IN GENERAL.—An agreement under
22 this section shall be effective for an initial pe-
23 riod of not less than 12 months and shall be
24 automatically renewed for a period of not less

1 than 1 year unless terminated under subpara-
2 graph (B).

3 “(B) TERMINATION.—

4 “(i) BY THE SECRETARY.—The Sec-
5 retary may provide for termination of an
6 agreement under this section for a knowing
7 and willful violation of the requirements of
8 the agreement or other good cause shown.
9 Such termination shall not be effective ear-
10 lier than 30 days after the date of notice
11 to the manufacturer of such termination.
12 The Secretary shall provide, upon request,
13 a manufacturer with a hearing concerning
14 such a termination, and such hearing shall
15 take place prior to the effective date of the
16 termination with sufficient time for such
17 effective date to be repealed if the Sec-
18 retary determines appropriate.

19 “(ii) BY A MANUFACTURER.—A man-
20 ufacturer may terminate an agreement
21 under this section for any reason. Any
22 such termination shall be effective, with re-
23 spect to a plan year—

24 “(I) if the termination occurs be-
25 fore January 30 of a plan year, as of

1 the day after the end of the plan year;

2 and

3 “(II) if the termination occurs on
4 or after January 30 of a plan year, as
5 of the day after the end of the suc-
6 ceeding plan year.

7 “(iii) EFFECTIVENESS OF TERMI-
8 NATION.—Any termination under this sub-
9 paragraph shall not affect discounts for
10 applicable drugs of the manufacturer that
11 are due under the agreement before the ef-
12 fective date of its termination.

13 “(iv) NOTICE TO THIRD PARTY.—The
14 Secretary shall provide notice of such ter-
15 mination to a third party with a contract
16 under subsection (d)(3) within not less
17 than 30 days before the effective date of
18 such termination.

19 “(5) EFFECTIVE DATE OF AGREEMENT.—An
20 agreement under this section shall take effect on a
21 date determined appropriate by the Secretary, which
22 may be at the start of a calendar quarter.

23 “(c) DUTIES DESCRIBED.—The duties described in
24 this subsection are the following:

1 “(1) ADMINISTRATION OF PROGRAM.—Admin-
2 istering the program, including—

3 “(A) the determination of the amount of
4 the discounted price of an applicable drug of a
5 manufacturer;

6 “(B) the establishment of procedures
7 under which discounted prices are provided to
8 applicable beneficiaries at pharmacies or by
9 mail order service at the point-of-sale of an ap-
10 plicable drug;

11 “(C) the establishment of procedures to
12 ensure that, not later than the applicable num-
13 ber of calendar days after the dispensing of an
14 applicable drug by a pharmacy or mail order
15 service, the pharmacy or mail order service is
16 reimbursed for an amount equal to the dif-
17 ference between—

18 “(i) the negotiated price of the appli-
19 cable drug; and

20 “(ii) the discounted price of the appli-
21 cable drug;

22 “(D) the establishment of procedures to
23 ensure that the discounted price for an applica-
24 ble drug under this section is applied before any
25 coverage or financial assistance under other

1 health benefit plans or programs that provide
2 coverage or financial assistance for the pur-
3 chase or provision of prescription drug coverage
4 on behalf of applicable beneficiaries as the Sec-
5 retary may specify; and

6 “(E) providing a reasonable dispute resolu-
7 tion mechanism to resolve disagreements be-
8 tween manufacturers, applicable beneficiaries,
9 and the third party with a contract under sub-
10 section (d)(3).

11 “(2) MONITORING COMPLIANCE.—

12 “(A) IN GENERAL.—The Secretary shall
13 monitor compliance by a manufacturer with the
14 terms of an agreement under this section.

15 “(B) NOTIFICATION.—If a third party
16 with a contract under subsection (d)(3) deter-
17 mines that the manufacturer is not in compli-
18 ance with such agreement, the third party shall
19 notify the Secretary of such noncompliance for
20 appropriate enforcement under subsection (e).

21 “(3) COLLECTION OF DATA FROM PRESCRIP-
22 TION DRUG PLANS AND MA–PD PLANS.—The Sec-
23 retary may collect appropriate data from prescrip-
24 tion drug plans and MA–PD plans in a timeframe

1 that allows for discounted prices to be provided for
2 applicable drugs under this section.

3 “(d) ADMINISTRATION.—

4 “(1) IN GENERAL.—Subject to paragraph (2),
5 the Secretary shall provide for the implementation of
6 this section, including the performance of the duties
7 described in subsection (c).

8 “(2) LIMITATION.—In providing for the imple-
9 mentation of this section, the Secretary shall not re-
10 ceive or distribute any funds of a manufacturer
11 under the program.

12 “(3) CONTRACT WITH THIRD PARTIES.—The
13 Secretary shall enter into a contract with 1 or more
14 third parties to administer the requirements estab-
15 lished by the Secretary in order to carry out this
16 section. At a minimum, the contract with a third
17 party under the preceding sentence shall require
18 that the third party—

19 “(A) receive and transmit information be-
20 tween the Secretary, manufacturers, and other
21 individuals or entities the Secretary determines
22 appropriate;

23 “(B) receive, distribute, or facilitate the
24 distribution of funds of manufacturers to ap-
25 propriate individuals or entities in order to

1 meet the obligations of manufacturers under
2 agreements under this section;

3 “(C) provide adequate and timely informa-
4 tion to manufacturers, consistent with the
5 agreement with the manufacturer under this
6 section, as necessary for the manufacturer to
7 fulfill its obligations under this section; and

8 “(D) permit manufacturers to conduct
9 periodic audits, directly or through contracts, of
10 the data and information used by the third
11 party to determine discounts for applicable
12 drugs of the manufacturer under the program.

13 “(4) PERFORMANCE REQUIREMENTS.—The
14 Secretary shall establish performance requirements
15 for a third party with a contract under paragraph
16 (3) and safeguards to protect the independence and
17 integrity of the activities carried out by the third
18 party under the program under this section.

19 “(5) ADMINISTRATION.—Chapter 35 of title 44,
20 United States Code, shall not apply to the program
21 under this section.

22 “(6) FUNDING.—For purposes of carrying out
23 this section, the Secretary shall provide for the
24 transfer, from the Federal Supplementary Medical
25 Insurance Trust Fund under section 1841 to the

1 Centers for Medicare & Medicaid Services Program
2 Management Account, of \$4,000,000 for each of fis-
3 cal years 2021 through 2024, to remain available
4 until expended.

5 “(e) ENFORCEMENT.—

6 “(1) AUDITS.—Each manufacturer with an
7 agreement in effect under this section shall be sub-
8 ject to periodic audit by the Secretary.

9 “(2) CIVIL MONEY PENALTY.—

10 “(A) IN GENERAL.—The Secretary shall
11 impose a civil money penalty on a manufacturer
12 that fails to provide applicable beneficiaries dis-
13 counts for applicable drugs of the manufacturer
14 in accordance with such agreement for each
15 such failure in an amount the Secretary deter-
16 mines is commensurate with the sum of—

17 “(i) the amount that the manufac-
18 turer would have paid with respect to such
19 discounts under the agreement, which will
20 then be used to pay the discounts which
21 the manufacturer had failed to provide;
22 and

23 “(ii) 25 percent of such amount.

24 “(B) APPLICATION.—The provisions of
25 section 1128A (other than subsections (a) and

1 (b)) shall apply to a civil money penalty under
2 this paragraph in the same manner as such
3 provisions apply to a penalty or proceeding
4 under section 1128A(a).

5 “(f) CLARIFICATION REGARDING AVAILABILITY OF
6 OTHER COVERED PART D DRUGS.—Nothing in this sec-
7 tion shall prevent an applicable beneficiary from pur-
8 chasing a covered part D drug that is not an applicable
9 drug (including a generic drug or a drug that is not on
10 the formulary of the prescription drug plan or MA–PD
11 plan that the applicable beneficiary is enrolled in).

12 “(g) DEFINITIONS.—In this section:

13 “(1) APPLICABLE BENEFICIARY.—The term
14 ‘applicable beneficiary’ means an individual who, on
15 the date of dispensing a covered part D drug—

16 “(A) is enrolled in a prescription drug plan
17 or an MA–PD plan;

18 “(B) is not enrolled in a qualified retiree
19 prescription drug plan; and

20 “(C) has incurred costs for covered part D
21 drugs in the year that are above the annual de-
22 ductible specified in section 1860D–2(b)(1) for
23 such year.

1 “(2) APPLICABLE DRUG.—The term ‘applicable
2 drug’ means, with respect to an applicable bene-
3 ficiary, a covered part D drug—

4 “(A) approved under a new drug applica-
5 tion under section 505(c) of the Federal Food,
6 Drug, and Cosmetic Act or, in the case of a bio-
7 logic product, licensed under section 351 of the
8 Public Health Service Act (including a product
9 licensed under subsection (k) of such section
10 351); and

11 “(B)(i) if the PDP sponsor of the prescrip-
12 tion drug plan or the MA organization offering
13 the MA–PD plan uses a formulary, which is on
14 the formulary of the prescription drug plan or
15 MA–PD plan that the applicable beneficiary is
16 enrolled in;

17 “(ii) if the PDP sponsor of the prescrip-
18 tion drug plan or the MA organization offering
19 the MA–PD plan does not use a formulary, for
20 which benefits are available under the prescrip-
21 tion drug plan or MA–PD plan that the appli-
22 cable beneficiary is enrolled in; or

23 “(iii) is provided through an exception or
24 appeal.

1 “(3) APPLICABLE NUMBER OF CALENDAR
2 DAYS.—The term ‘applicable number of calendar
3 days’ means—

4 “(A) with respect to claims for reimburse-
5 ment submitted electronically, 14 days; and

6 “(B) with respect to claims for reimburse-
7 ment submitted otherwise, 30 days.

8 “(4) DISCOUNTED PRICE.—

9 “(A) IN GENERAL.—Except as provided in
10 subparagraph (B), the term ‘discounted price’
11 means 90 percent of the negotiated price of the
12 applicable drug of a manufacturer.

13 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-
14 PENSED FOR SUBSIDY ELIGIBLE INDIVID-
15 UALS.—

16 “(i) IN GENERAL.—In the case of an
17 applicable drug of a specified manufacturer
18 (as defined in clause (ii)) that is dispensed
19 for an applicable beneficiary who is a sub-
20 sidy eligible individual (as defined in sec-
21 tion 1860D–14(a)(3), the term ‘discounted
22 price’ means the specified LIS percent (as
23 defined in clause (iii)) of the negotiated
24 price of the applicable drug of the manu-
25 facturer.

1 “(ii) SPECIFIED MANUFACTURER.—In
2 this subparagraph, the term ‘specified
3 manufacturer’ means a manufacturer of an
4 applicable drug for which, in the calendar
5 year 2 years prior to the current plan year
6 (referred to in this clause as the ‘applicable
7 period’), the total reimbursement under
8 this title during the applicable period rep-
9 resented less than 1 percent of the total re-
10 imbursement under this title for all pre-
11 scription drugs during such period.

12 “(iii) SPECIFIED LIS PERCENT.—In
13 this subparagraph, the term ‘specified LIS
14 percent’ means—

15 “(I) for 2024, 98 percent;

16 “(II) for 2025, 97 percent;

17 “(III) for 2026, 96 percent;

18 “(IV) for 2027, 95 percent;

19 “(V) for 2028, 94 percent;

20 “(VI) for 2029, 93 percent;

21 “(VII) for 2030, 92 percent;

22 “(VIII) for 2031, 91 percent;

23 and

24 “(IX) for 2032 and each subse-
25 quent year, 90 percent.

1 “(C) CLARIFICATION.—Nothing in this
2 section shall be construed as affecting the re-
3 sponsibility of an applicable beneficiary for pay-
4 ment of a dispensing fee for an applicable drug.

5 “(5) MANUFACTURER.—The term ‘manufac-
6 turer’ means any entity which is engaged in the pro-
7 duction, preparation, propagation, compounding,
8 conversion, or processing of prescription drug prod-
9 ucts, either directly or indirectly by extraction from
10 substances of natural origin, or independently by
11 means of chemical synthesis, or by a combination of
12 extraction and chemical synthesis. Such term does
13 not include a wholesale distributor of drugs or a re-
14 tail pharmacy licensed under State law.

15 “(6) NEGOTIATED PRICE.—The term ‘nego-
16 tiated price’ has the meaning given such term in sec-
17 tion 1860D–2(d)(1)(B), except that such negotiated
18 price shall not include any dispensing fee for the ap-
19 plicable drug.

20 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
21 PLAN.—The term ‘qualified retiree prescription drug
22 plan’ has the meaning given such term in section
23 1860D–22(a)(2).”.

24 “(2) SUNSET OF MEDICARE COVERAGE GAP DIS-
25 COUNT PROGRAM.—Section 1860D–14A of the So-

1 cial Security Act (42 U.S.C. 1395–114a) is amend-
2 ed—

3 (A) in subsection (a), in the first sentence,
4 by striking “The Secretary” and inserting
5 “Subject to subsection (h), the Secretary”; and

6 (B) by adding at the end the following new
7 subsection:

8 “(h) SUNSET OF PROGRAM.—

9 “(1) IN GENERAL.—The program shall not
10 apply to applicable drugs dispensed on or after Janu-
11 uary 1, 2024, and, subject to paragraph (2), agree-
12 ments under this section shall be terminated as of
13 such date.

14 “(2) CONTINUED APPLICATION FOR APPLICA-
15 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
16 provisions of this section (including all responsibil-
17 ities and duties) shall continue to apply after Janu-
18 ary 1, 2024, with respect to applicable drugs dis-
19 pensed prior to such date.”.

20 (3) INCLUSION OF ACTUARIAL VALUE OF MANU-
21 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11
22 of the Social Security Act (42 U.S.C. 1395w–111)
23 is amended—

24 (A) in subsection (b)(2)(C)(iii)—

1 (i) by striking “assumptions regarding
2 the reinsurance” and inserting “an actu-
3 arial valuation of—

4 “(I) the reinsurance”; and

5 (ii) by adding at the end the fol-
6 lowing:

7 “(II) for 2024 and each subse-
8 quent year, the manufacturer dis-
9 counts provided under section 1860D-
10 14B subtracted from the actuarial
11 value to produce such bid; and”;

12 (B) in subsection (c)(1)(C)—

13 (i) by striking “an actuarial valuation
14 of the reinsurance” and inserting “an actu-
15 arial valuation of—

16 “(i) the reinsurance”;

17 (ii) in clause (i), as added by clause
18 (i) of this subparagraph, by adding “and”
19 at the end; and

20 (iii) by adding at the end the fol-
21 lowing:

22 “(ii) for 2024 and each subsequent
23 year, the manufacturer discounts provided
24 under section 1860D-14B;”.

1 (4) CLARIFICATION REGARDING EXCLUSION OF
2 MANUFACTURER DISCOUNTS FROM TROOP.—Section
3 1860D–2(b)(4) of the Social Security Act (42
4 U.S.C. 1395w–102(b)(4)) is amended—

5 (A) in subparagraph (C), by inserting “and
6 subject to subparagraph (F)” after “subpara-
7 graph (E)”;

8 (B) by adding at the end the following new
9 subparagraph:

10 “(F) CLARIFICATION REGARDING EXCLU-
11 SION OF MANUFACTURER DISCOUNTS.—In ap-
12 plying subparagraph (A), incurred costs shall
13 not include any manufacturer discounts pro-
14 vided under section 1860D–14B.”.

15 (d) DETERMINATION OF ALLOWABLE REINSURANCE
16 COSTS.—Section 1860D–15(b) of the Social Security Act
17 (42 U.S.C. 1395w–115(b)) is amended—

18 (1) in paragraph (2)—

19 (A) by striking “COSTS.—For purposes”
20 and inserting: “COSTS.—

21 “(A) IN GENERAL.—Subject to subpara-
22 graph (B), for purposes”; and

23 (B) by adding at the end the following new
24 subparagraph:

1 “(B) INCLUSION OF MANUFACTURER DIS-
2 COUNTS ON APPLICABLE DRUGS.—For purposes
3 of applying subparagraph (A), the term ‘allow-
4 able reinsurance costs’ shall include the portion
5 of the negotiated price (as defined in section
6 1860D–14B(g)(6)) of an applicable drug (as
7 defined in section 1860D–14B(g)(2)) that was
8 paid by a manufacturer under the manufacturer
9 discount program under section 1860D–14B.”;
10 and

11 (2) in paragraph (3)—

12 (A) in the first sentence, by striking “For
13 purposes” and inserting “Subject to paragraph
14 (2)(B), for purposes”; and

15 (B) in the second sentence, by inserting
16 “or, in the case of an applicable drug, by a
17 manufacturer” after “by the individual or
18 under the plan”.

19 (e) UPDATING RISK ADJUSTMENT METHODOLOGIES
20 TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—
21 Section 1860D–15(e) of the Social Security Act (42
22 U.S.C. 1395w–115(e)) is amended by adding at the end
23 the following new paragraph:

24 “(3) UPDATING RISK ADJUSTMENT METH-
25 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-

1 TION REDESIGN.—The Secretary shall update the
2 risk adjustment methodologies used to adjust bid
3 amounts pursuant to this subsection as appropriate
4 to take into account changes in benefits under this
5 part pursuant to the amendments made by section
6 2 of the Seniors Prescription Drug Relief Act.”.

7 (f) CONDITIONS FOR COVERAGE OF DRUGS UNDER
8 THIS PART.—Section 1860D–43 of the Social Security
9 Act (42 U.S.C. 1395w–153) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (2), by striking “and” at
12 the end;

13 (B) in paragraph (3), by striking the pe-
14 riod at the end and inserting a semicolon; and

15 (C) by adding at the end the following new
16 paragraphs:

17 “(4) participate in the manufacturer discount
18 program under section 1860D–14B;

19 “(5) have entered into and have in effect an
20 agreement described in subsection (b) of such sec-
21 tion 1860D–14B with the Secretary; and

22 “(6) have entered into and have in effect, under
23 terms and conditions specified by the Secretary, a
24 contract with a third party that the Secretary has

1 entered into a contract with under subsection (d)(3)
2 of such section 1860D–14B.”;

3 (2) by striking subsection (b) and inserting the
4 following:

5 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
6 of subsection (a) shall apply to covered part D drugs dis-
7 pensed under this part on or after January 1, 2011, and
8 before January 1, 2024, and paragraphs (4) through (6)
9 of such subsection shall apply to covered part D drugs
10 dispensed on or after January 1, 2024.”; and

11 (3) in subsection (c), by striking paragraph (2)
12 and inserting the following:

13 “(2) the Secretary determines that in the period
14 beginning on January 1, 2011, and ending on De-
15 cember 31, 2011 (with respect to paragraphs (1)
16 through (3) of subsection (a)), or the period begin-
17 ning on January 1, 2024, and ending December 31,
18 2024 (with respect to paragraphs (4) through (6) of
19 such subsection), there were extenuating cir-
20 cumstances.”.

21 (g) CONFORMING AMENDMENTS.—

22 (1) Section 1860D–2 of the Social Security Act
23 (42 U.S.C. 1395w–102) is amended—

24 (A) in subsection (a)(2)(A)(i)(I), by strik-
25 ing “, or an increase in the initial” and insert-

1 ing “or for a year preceding 2024 an increase
2 in the initial”;

3 (B) in subsection (c)(1)(C)—

4 (i) in the subparagraph heading, by
5 striking “AT INITIAL COVERAGE LIMIT”;
6 and

7 (ii) by inserting “for a year preceding
8 2024 or the annual out-of-pocket threshold
9 specified in subsection (b)(4)(B) for the
10 year for 2024 and each subsequent year”
11 after “subsection (b)(3) for the year” each
12 place it appears; and

13 (C) in subsection (d)(1)(A), by striking “or
14 an initial” and inserting “or for a year pre-
15 ceding 2024 an initial”.

16 (2) Section 1860D–4(a)(4)(B)(i) of the Social
17 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
18 amended by striking “the initial” and inserting “for
19 a year preceding 2024, the initial”.

20 (3) Section 1860D–14(a) of the Social Security
21 Act (42 U.S.C. 1395w–114(a)) is amended—

22 (A) in paragraph (1)—

23 (i) in subparagraph (C), by striking
24 “The continuation” and inserting “For a
25 year preceding 2024, the continuation”;

1 (ii) in subparagraph (D)(iii), by strik-
2 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
3 ing “1860D–2(b)(4)(A)(i)(I)(aa)”;

4 (iii) in subparagraph (E), by striking
5 “The elimination” and inserting “For a
6 year preceding 2024, the elimination”; and
7 (B) in paragraph (2)—

8 (i) in subparagraph (C), by striking
9 “The continuation” and inserting “For a
10 year preceding 2024, the continuation”;
11 and

12 (ii) in subparagraph (E)—

13 (I) by inserting “for a year pre-
14 ceding 2024,” after “subsection (e)”;
15 and

16 (II) by striking “1860D–
17 2(b)(4)(A)(i)(I)” and inserting
18 “1860D–2(b)(4)(A)(i)(I)(aa)”.

19 (4) Section 1860D–21(d)(7) of the Social Secu-
20 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended
21 by striking “section 1860D–2(b)(B)(4)(B)(i)” and
22 inserting “section 1860D–2(b)(B)(4)(C)(i)”.

23 (5) Section 1860D–22(a)(2)(A) of the Social
24 Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is
25 amended—

1 (A) by striking “the value of any discount”
2 and inserting the following: “the value of—

3 “(i) for years prior to 2024, any dis-
4 count”;

5 (B) in clause (i), as inserted by subpara-
6 graph (A) of this paragraph, by striking the pe-
7 riod at the end and inserting “; and”; and

8 (C) by adding at the end the following new
9 clause:

10 “(ii) for 2024 and each subsequent
11 year, any discount provided pursuant to
12 section 1860D–14B.”.

13 (6) Section 1860D–41(a)(6) of the Social Secu-
14 rity Act (42 U.S.C. 1395w–151(a)(6)) is amended—

15 (A) by inserting “for a year before 2024”
16 after “1860D–2(b)(3)”; and

17 (B) by inserting “for such year” before the
18 period.

19 (h) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to plan year 2024 and subsequent
21 plan years.

22 **SEC. 210. PUBLIC DISCLOSURE OF DRUG DISCOUNTS AND**
23 **OTHER PHARMACY BENEFIT MANAGER (PBM)**
24 **PROVISIONS.**

25 (a) PUBLIC DISCLOSURE OF DRUG DISCOUNTS.—

1 (1) IN GENERAL.—Section 1150A of the Social
2 Security Act (42 U.S.C. 1320b–23) is amended—

3 (A) in subsection (c), in the matter pre-
4 ceding paragraph (1), by striking “this section”
5 and inserting “subsection (b)(1)”; and

6 (B) by adding at the end the following new
7 subsection:

8 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-
9 TION.—

10 “(1) IN GENERAL.—Subject to paragraphs (2)
11 and (3), in order to allow patients and employers to
12 compare PBMs’ ability to negotiate rebates, dis-
13 counts, and price concessions and the amount of
14 such rebates, discounts, and price concessions that
15 are passed through to plan sponsors, not later than
16 July 1, 2025, the Secretary shall make available on
17 the Internet website of the Department of Health
18 and Human Services the information provided to the
19 Secretary and described in paragraphs (2) and (3)
20 of subsection (b) with respect to each PBM.

21 “(2) LAG IN DATA.—The information made
22 available in a plan year under paragraph (1) shall
23 not include information with respect to such plan
24 year or the two preceding plan years.

1 “(3) CONFIDENTIALITY.—The Secretary shall
2 ensure that such information is displayed in a man-
3 ner that prevents the disclosure of information on
4 rebates, discounts, and price concessions with re-
5 spect to an individual drug or an individual PDP
6 sponsor, MA organization, or qualified health bene-
7 fits plan.”.

8 (2) EFFECTIVE DATE.—The amendment made
9 by paragraph (1)(A) shall take effect on January 1,
10 2025.

11 (b) PLAN AUDIT OF PHARMACY BENEFIT MANAGER
12 DATA.—Section 1860D–2(d)(3) of the Social Security Act
13 (42 U.S.C. 1395w–102(d)(3)) is amended—

14 (1) by striking “AUDITS.—To protect” and in-
15 serting the following: “AUDITS.—

16 “(A) AUDITS OF PLANS BY THE SEC-
17 RETARY.—To protect”; and

18 (2) by adding at the end the following new sub-
19 paragraph:

20 “(B) AUDITS OF PHARMACY BENEFIT
21 MANAGERS BY PDP SPONSORS AND MA ORGANI-
22 ZATIONS.—

23 “(i) IN GENERAL.—Beginning Janu-
24 ary 1, 2025, in order to ensure that—

1 “(I) contracting terms between a
2 PDP sponsor offering a prescription
3 drug plan or an MA organization of-
4 fering an MA–PD plan and its con-
5 tracted or owned pharmacy benefit
6 manager are met; and

7 “(II) the PDP sponsor and MA
8 organization can account for the cost
9 of each covered part D drug net of all
10 direct and indirect remuneration;

11 the PDP sponsor or MA organization shall
12 conduct financial audits.

13 “(ii) INDEPENDENT THIRD PARTY.—
14 An audit described in clause (i) shall—

15 “(I) be conducted by an inde-
16 pendent third party; and

17 “(II) account and reconcile flows
18 of funds that determine the net cost
19 of covered part D drugs, including di-
20 rect and indirect remuneration from
21 drug manufacturers and pharmacies
22 or provided to pharmacies.

23 “(iii) REBATE AGREEMENTS.—A PDP
24 sponsor and an MA organization shall re-
25 quire pharmacy benefit managers to make

1 rebate contracts with drug manufacturers
2 made on their behalf available under audits
3 described in clause (i).

4 “(iv) CONFIDENTIALITY AGREEMENTS.—Audits described in clause (i)
5 shall be subject to confidentiality agree-
6 ments to prevent, except as required under
7 clause (vii), the redisclosure of data trans-
8 mitted under the audit.

9
10 “(v) FREQUENCY.—A financial audit
11 under clause (i) shall be conducted periodi-
12 cally (but in no case less frequently than
13 once every 2 years).

14 “(vi) TIMEFRAME FOR PBM TO PRO-
15 VIDE INFORMATION.—A PDP sponsor and
16 an MA organization shall require that a
17 pharmacy benefit manager that is being
18 audited under clause (i) provide (as part of
19 their contracting agreement) the requested
20 information to the independent third party
21 conducting the audit within 45 days of the
22 date of the request.

23 “(vii) SUBMISSION OF AUDIT REPORTS
24 TO THE SECRETARY.—

1 “(I) IN GENERAL.—A PDP spon-
2 sor and an MA organization shall sub-
3 mit to the Secretary the final report
4 on any audit conducted under clause
5 (i) within 30 days of the PDP sponsor
6 or MA organization receiving the re-
7 port from the independent third party
8 conducting the audit.

9 “(II) REVIEW.—The Secretary
10 shall review final reports submitted
11 under clause (i) to determine the ex-
12 tent to which the goals specified in
13 subclauses (I) and (II) of subpara-
14 graph (B)(i) are met.

15 “(III) CONFIDENTIALITY.—Not-
16 withstanding any other provision of
17 law, information disclosed in a report
18 submitted under clause (i) related to
19 the net cost of a covered part D drug
20 is confidential and shall not be dis-
21 closed by the Secretary or a Medicare
22 contractor.

23 “(viii) NOTICE OF NONCOMPLI-
24 ANCE.—A PDP sponsor and an MA orga-
25 nization shall notify the Secretary if any

1 pharmacy benefit manager is not com-
2 plying with requests for access to informa-
3 tion required under an audit under clause
4 (i).

5 “(ix) CIVIL MONETARY PENALTIES.—

6 “(I) IN GENERAL.—Subject to
7 subclause (II), if the Secretary deter-
8 mines that a PDP sponsor or an MA
9 organization has failed to conduct an
10 audit under clause (i), the Secretary
11 may impose a civil monetary penalty
12 of not more than \$10,000 for each
13 day of such noncompliance.

14 “(II) PROCEDURE.—The provi-
15 sions of section 1128A, other than
16 subsections (a) and (b) and the first
17 sentence of subsection (c)(1) of such
18 section, shall apply to civil monetary
19 penalties under this clause in the
20 same manner as such provisions apply
21 to a penalty or proceeding under sec-
22 tion 1128A.”.

23 (c) DISCLOSURE TO PHARMACY OF POST-POINT-OF-
24 SALE PHARMACY PRICE CONCESSIONS AND INCENTIVE

1 PAYMENTS.—Section 1860D–2(d)(2) of the Social Secu-
2 rity Act (42 U.S.C. 1395w–102(d)(2)) is amended—

3 (1) by striking “DISCLOSURE.—A PDP spon-
4 sor” and inserting the following: “DISCLOSURE.—

5 “(A) TO THE SECRETARY.—A PDP spon-
6 sor”; and

7 (2) by adding at the end the following new sub-
8 paragraph:

9 “(B) TO PHARMACIES.—

10 “(i) IN GENERAL.—For plan year
11 2025 and subsequent plan years, a PDP
12 sponsor offering a prescription drug plan
13 and an MA organization offering an MA-
14 PD plan shall report any pharmacy price
15 concession or incentive payment that oc-
16 curs with respect to a pharmacy after pay-
17 ment for covered part D drugs at the
18 point-of-sale, including by an intermediary
19 organization with which a PDP sponsor or
20 MA organization has contracted, to the
21 pharmacy.

22 “(ii) TIMING.—The reporting of price
23 concessions and incentive payments to a
24 pharmacy under clause (i) shall be made

1 on a periodic basis (but in no case less fre-
2 quently than annually).

3 “(iii) CLAIM LEVEL.—The reporting
4 of price concessions and incentive pay-
5 ments to a pharmacy under clause (i) shall
6 be at the claim level or approximated at
7 the claim level if the price concession or in-
8 centive payment was applied at a level
9 other than at the claim level.”.

10 (d) DISCLOSURE OF P&T COMMITTEE CONFLICTS OF
11 INTEREST.—

12 (1) IN GENERAL.—Section 1860D–4(b)(3)(A)
13 of the Social Security Act (42 U.S.C. 1395w–
14 104(b)(3)(A)) is amended by adding at the end the
15 following new clause:

16 “(iii) DISCLOSURE OF CONFLICTS OF
17 INTEREST.—With respect to plan year
18 2025 and subsequent plan years, a PDP
19 sponsor of a prescription drug plan and an
20 MA organization offering an MA–PD plan
21 shall, as part of its bid submission under
22 section 1860D–11(b), provide the Sec-
23 retary with a completed statement of fi-
24 nancial conflicts of interest, including with
25 manufacturers, from each member of any

1 pharmacy and therapeutic committee used
2 by the sponsor or organization pursuant to
3 this paragraph.”.

4 (2) INCLUSION IN BID.—Section 1860D–
5 11(b)(2) of the Social Security Act (42 U.S.C.
6 1395w–111(b)(2)) is amended—

7 (A) by redesignating subparagraph (F) as
8 subparagraph (G); and

9 (B) by inserting after subparagraph (E)
10 the following new subparagraph:

11 “(F) P&T COMMITTEE CONFLICTS OF IN-
12 TEREST.—The information required to be dis-
13 closed under section 1860D–4(b)(3)(A)(iii).”.

14 (e) INFORMATION ON DIRECT AND INDIRECT REMU-
15 NERATION REQUIRED TO BE INCLUDED IN BID.—Section
16 1860D–11(b) of the Social Security Act (42 U.S.C.
17 1395w–111(b)) is amended—

18 (1) in paragraph (1), by adding at the end the
19 following new sentence: “With respect to actual
20 amounts of direct and indirect remuneration sub-
21 mitted pursuant to clause (v) of paragraph (2), such
22 amounts shall be consistent with data reported to
23 the Secretary in a prior year.”; and

24 (2) in paragraph (2)(C)—

1 (A) in clause (iii), by striking “and” at the
2 end;

3 (B) in clause (iv), by striking the period at
4 the end and inserting the following: “, and, with
5 respect to plan year 2025 and subsequent plan
6 years, actual and projected administrative ex-
7 penses assumed in the bid, categorized by the
8 type of such expense, including actual and pro-
9 jected price concessions retained by a pharmacy
10 benefit manager; and”;

11 (C) by adding at the end the following new
12 clause:

13 “(v) with respect to plan year 2025
14 and subsequent plan years, actual and pro-
15 jected direct and indirect remuneration,
16 categorized as received from each of the
17 following:

18 “(I) A pharmacy.

19 “(II) A manufacturer.

20 “(III) A pharmacy benefit man-
21 ager.

22 “(IV) Other entities, as deter-
23 mined by the Secretary.”

1 **SEC. 211. PUBLIC DISCLOSURE OF DIRECT AND INDIRECT**
2 **REMUNERATION REVIEW AND AUDIT RE-**
3 **SULTS.**

4 Section 1860D–42 of the Social Security Act (42
5 U.S.C. 1395w–152) is amended by adding at the end the
6 following new subsection:

7 “(e) PUBLIC DISCLOSURE OF DIRECT AND INDIRECT
8 REMUNERATION REVIEW AND FINANCIAL AUDIT RE-
9 SULTS.—

10 “(1) DIR REVIEW RESULTS.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B), in 2023 and each subse-
13 quent year, the Secretary shall make available
14 to the public on the Internet website of the
15 Centers for Medicare & Medicaid Services infor-
16 mation on discrepancies related to summary
17 and detailed DIR reports submitted by PDP
18 sponsors pursuant to section 1860D–15 across
19 all prescription drug plans based on the most
20 recent data available. Information made avail-
21 able under this subparagraph shall include the
22 following:

23 “(i) The number of potential errors
24 identified by the Secretary for PDP spon-
25 sors to review.

1 “(ii) The extent to which PDP spon-
2 sors resubmitted DIR reports to make
3 changes for previous contract years.

4 “(iii) The extent to which resubmitted
5 DIR reports resulted in an increase or de-
6 crease in DIR in a previous contract year.

7 “(B) EXCLUSION OF CERTAIN SUBMIS-
8 SIONS IN CALCULATION.—The Secretary shall
9 exclude any information in DIR reports sub-
10 mitted with respect to PACE programs under
11 section 1894 (pursuant to section 1860D–21(f))
12 and qualified retiree prescription drug plans (as
13 defined in section 1860D–22(a)(2)) from the
14 information that is made available to the public
15 under subparagraph (A).

16 “(2) FINANCIAL AUDIT RESULTS.—In 2023 and
17 each subsequent year, the Secretary shall make
18 available to the public on the Internet website of the
19 Centers for Medicare & Medicaid Services the results
20 of DIR audits required under section 1860D–
21 12(b)(3)(C). Information made available under this
22 paragraph shall include the following:

23 “(A) With respect to the year, the number
24 of PDP sponsors that received each of the fol-
25 lowing:

1 “(i) A notice of observations or find-
2 ings that required the sponsor to make
3 DIR report corrections.

4 “(ii) An unqualified audit opinion that
5 renders the audit closed.

6 “(iii) A qualified audit opinion that
7 requires the sponsor to submit a corrective
8 action plan to the Secretary.

9 “(iv) An adverse opinion, with a de-
10 scription of the types of actions that the
11 Secretary takes when issuing an adverse
12 opinion.

13 “(B) With respect to a preceding year:

14 “(i) The number of PDP sponsors
15 that reopened a previously closed reconcili-
16 ation as a result of an audit, including as
17 a result of DIR changes.

18 “(ii) The extent to which the Sec-
19 retary recouped an overpayment or made
20 an underpayment as a result of a reopen-
21 ing of a previously closed reconciliation.

22 “(3) DEFINITION OF DIR.—For purposes of
23 this subsection, the term ‘DIR’ means direct and in-
24 direct remuneration as defined in section 423.308 of

1 title 42, Code of Federal Regulations, or any suc-
2 cessor regulation.”.

3 **SEC. 212. IMPROVEMENTS TO PROVISION OF PARTS A AND**
4 **B CLAIMS DATA TO PRESCRIPTION DRUG**
5 **PLANS.**

6 (a) DATA USE.—

7 (1) IN GENERAL.—Paragraph (6) of section
8 1860D–4(c) of the Social Security Act (42 U.S.C.
9 1395w–104(c)), as added by section 50354 of divi-
10 sion E of the Bipartisan Budget Act of 2018 (Public
11 Law 115–123), relating to providing prescription
12 drug plans with parts A and B claims data to pro-
13 mote the appropriate use of medications and im-
14 prove health outcomes, is amended—

15 (A) in subparagraph (B)—

16 (i) by redesignating clauses (i), (ii),
17 and (iii) as subclauses (I), (II), and (III),
18 respectively, and moving such subclauses 2
19 ems to the right;

20 (ii) by striking “PURPOSES.—A PDP
21 sponsor” and inserting PURPOSES—

22 “(i) IN GENERAL.—A PDP sponsor.”;

23 and

24 (iii) by adding at the end the fol-
25 lowing new clause:

1 “(ii) CLARIFICATION.—The limitation
2 on data use under subparagraph (C)(i)
3 shall not apply to the extent that the PDP
4 sponsor is using the data provided to carry
5 out any of the purposes described in clause
6 (i).”; and

7 (B) in subparagraph (C)(i), by striking
8 “To inform” and inserting “Subject to subpara-
9 graph (B)(ii), to inform”.

10 (2) EFFECTIVE DATE.—The amendments made
11 by this subsection shall apply to plan years begin-
12 ning on or after January 1, 2025.

13 (b) MANNER OF PROVISION.—Subparagraph (D) of
14 such paragraph (6) is amended—

15 (1) by striking “DESCRIBED.—The data de-
16 scribed in this clause” and inserting “DESCRIBED.—

17 “(i) IN GENERAL.—The data de-
18 scribed in this subparagraph”; and

19 (2) by adding at the end the following new
20 clause:

21 “(ii) MANNER OF PROVISION.—

22 “(I) IN GENERAL.—Such data
23 may be provided pursuant to this
24 paragraph in the same manner as
25 data under the Part D Enhanced

1 Medication Therapy Management
2 model tested under section 1115A,
3 through Application Programming
4 Interface, or in another manner as de-
5 termined by the Secretary.

6 “(II) IMPLEMENTATION.—Not-
7 withstanding any other provision of
8 law, the Secretary may implement this
9 clause by program instruction or oth-
10 erwise.”.

11 (c) TECHNICAL CORRECTION.—Such paragraph (6)
12 is redesignated as paragraph (7).

13 **SEC. 213. MEDICARE PART D REBATE BY MANUFACTURERS.**

14 (a) IN GENERAL.—Part D of title XVIII of the Social
15 Security Act is amended by inserting after section 1860D-
16 14A (42 U.S.C. 1395w-114a) the following new section:

17 **“SEC. 1860D-14B. MANUFACTURER REBATE FOR CERTAIN**
18 **DRUGS WITH PRICES INCREASING FASTER**
19 **THAN INFLATION.**

20 “(a) IN GENERAL.—

21 “(1) IN GENERAL.—Subject to the provisions of
22 this section, in order for coverage to be available
23 under this part for a part D rebatable drug (as de-
24 fined in subsection (h)(1)) of a manufacturer (as de-
25 fined in section 1927(k)(5)) dispensed during an ap-

1 plicable year, the manufacturer must have entered
2 into and have in effect an agreement described in
3 subsection (b).

4 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT
5 COVERED UNDER AGREEMENTS.—Paragraph (1)
6 shall not apply to the dispensing of a covered part
7 D drug if—

8 “(A) the Secretary has made a determina-
9 tion that the availability of the drug is essential
10 to the health of beneficiaries under this part; or

11 “(B) the Secretary determines that in the
12 period beginning on January 1, 2025, and end-
13 ing on December 31, 2025, there were extenu-
14 ating circumstances.

15 “(3) APPLICABLE YEAR.—For purposes of this
16 section the term ‘applicable year’ means a year be-
17 ginning with 2025.

18 “(b) AGREEMENTS.—

19 “(1) TERMS OF AGREEMENT.—An agreement
20 described in this subsection, with respect to a manu-
21 facturer of a part D rebatable drug, is an agreement
22 under which the following shall apply:

23 “(A) SECRETARIAL PROVISION OF INFOR-
24 MATION.—Not later than 9 months after the
25 end of each applicable year with respect to

1 which the agreement is in effect, the Secretary,
2 for each part D rebatable drug of the manufac-
3 turer, shall report to the manufacturer the fol-
4 lowing for such year:

5 “(i) Information on the total number
6 of units (as defined in subsection (h)(2))
7 for each dosage form and strength with re-
8 spect to such part D rebatable drug and
9 year.

10 “(ii) Information on the amount (if
11 any) of the excess average manufacturer
12 price increase described in subsection
13 (c)(1)(B) for each dosage form and
14 strength with respect to such drug and
15 year.

16 “(iii) The rebate amount specified
17 under subsection (c) for each dosage form
18 and strength with respect to such drug and
19 year.

20 “(B) MANUFACTURER REQUIREMENTS.—
21 For each applicable year with respect to which
22 the agreement is in effect, the manufacturer of
23 the part D rebatable drug, for each dosage
24 form and strength with respect to such drug,
25 not later than 30 days after the date of receipt

1 from the Secretary of the information described
2 in subparagraph (A) for such year, shall pro-
3 vide to the Secretary a rebate that is equal to
4 the amount specified in subsection (c) for such
5 dosage form and strength with respect to such
6 drug for such year.

7 “(2) LENGTH OF AGREEMENT.—

8 “(A) IN GENERAL.—An agreement under
9 this section, with respect to a part D rebatable
10 drug, shall be effective for an initial period of
11 not less than one year and shall be automati-
12 cally renewed for a period of not less than one
13 year unless terminated under subparagraph
14 (B).

15 “(B) TERMINATION.—

16 “(i) BY SECRETARY.—The Secretary
17 may provide for termination of an agree-
18 ment under this section for violation of the
19 requirements of the agreement or other
20 good cause shown. Such termination shall
21 not be effective earlier than 30 days after
22 the date of notice of such termination. The
23 Secretary shall provide, upon request, a
24 manufacturer with a hearing concerning
25 such a termination, but such hearing shall

1 not delay the effective date of the termi-
2 nation.

3 “(ii) BY A MANUFACTURER.—A man-
4 ufacturer may terminate an agreement
5 under this section for any reason. Any
6 such termination shall be effective, with re-
7 spect to a plan year—

8 “(I) if the termination occurs be-
9 fore January 30 of the plan year, as
10 of the day after the end of the plan
11 year; and

12 “(II) if the termination occurs on
13 or after January 30 of the plan year,
14 as of the day after the end of the suc-
15 ceeding plan year.

16 “(C) EFFECTIVENESS OF TERMINATION.—
17 Any termination under this paragraph shall not
18 affect rebates due under the agreement under
19 this section before the effective date of its ter-
20 mination.

21 “(D) DELAY BEFORE REENTRY.—In the
22 case of any agreement under this section with
23 a manufacturer that is terminated in a plan
24 year, the Secretary may not enter into another
25 such agreement with the manufacturer (or a

1 successor manufacturer) before the subsequent
2 plan year, unless the Secretary finds good cause
3 for an earlier reinstatement of such an agree-
4 ment.

5 “(c) REBATE AMOUNT.—

6 “(1) IN GENERAL.—For purposes of this sec-
7 tion, the amount specified in this subsection for a
8 dosage form and strength with respect to a part D
9 rebtable drug and applicable year is, subject to sub-
10 paragraphs (B) and (C) of paragraph (5), the
11 amount equal to the product of—

12 “(A) the total number of units of such dos-
13 age form and strength with respect to such part
14 D rebtable drug and year; and

15 “(B) the amount (if any) by which—

16 “(i) the annual manufacturer price
17 (as determined in paragraph (2)) paid for
18 such dosage form and strength with re-
19 spect to such part D rebtable drug for the
20 year; exceeds

21 “(ii) the inflation-adjusted payment
22 amount determined under paragraph (3)
23 for such dosage form and strength with re-
24 spect to such part D rebtable drug for the
25 year.

1 “(2) DETERMINATION OF ANNUAL MANUFAC-
2 TURER PRICE.—The annual manufacturer price de-
3 termined under this paragraph for a dosage form
4 and strength, with respect to a part D rebatable
5 drug and an applicable year, is the sum of the prod-
6 ucts of—

7 “(A) the average manufacturer price (as
8 defined in subsection (h)(6)) of such dosage
9 form and strength, as calculated for a unit of
10 such drug, with respect to each of the calendar
11 quarters of such year; and

12 “(B) the ratio of—

13 “(i) the total number of units of such
14 dosage form and strength dispensed during
15 each such calendar quarter of such year; to

16 “(ii) the total number of units of such
17 dosage form and strength dispensed during
18 such year.

19 “(3) DETERMINATION OF INFLATION-ADJUSTED
20 PAYMENT AMOUNT.—The inflation-adjusted payment
21 amount determined under this paragraph for a dos-
22 age form and strength with respect to a part D
23 rebatable drug for an applicable year, subject to sub-
24 paragraphs (A) and (D) of paragraph (5), is—

1 “(A) the benchmark year manufacturer
2 price determined under paragraph (4) for such
3 dosage form and strength with respect to such
4 drug and an applicable year; increased by

5 “(B) the percentage by which the applica-
6 ble year CPI-U (as defined in subsection
7 (h)(5)) for the applicable year exceeds the
8 benchmark period CPI-U (as defined in sub-
9 section (h)(4)).

10 “(4) DETERMINATION OF BENCHMARK YEAR
11 MANUFACTURER PRICE.—The benchmark year man-
12 ufacturer price determined under this paragraph for
13 a dosage form and strength, with respect to a part
14 D rebatable drug and an applicable year, is the sum
15 of the products of—

16 “(A) the average manufacturer price (as
17 defined in subsection (h)(6)) of such dosage
18 form and strength, as calculated for a unit of
19 such drug, with respect to each of the calendar
20 quarters of the payment amount benchmark
21 year (as defined in subsection (h)(3)); and

22 “(B) the ratio of—

23 “(i) the total number of units of such
24 dosage form and strength dispensed during

1 each such calendar quarter of such pay-
2 ment amount benchmark year; to

3 “(ii) the total number of units of such
4 dosage form and strength dispensed during
5 such payment amount benchmark year.

6 “(5) SPECIAL TREATMENT OF CERTAIN DRUGS
7 AND EXEMPTION.—

8 “(A) SUBSEQUENTLY APPROVED DRUGS.—

9 In the case of a part D rebatable drug first ap-
10 proved or licensed by the Food and Drug Ad-
11 ministration after January 1, 2016, subpara-
12 graphs (A) and (B) of paragraph (4) shall be
13 applied as if the term ‘payment amount bench-
14 mark year’ were defined under subsection
15 (h)(3) as the first calendar year beginning after
16 the day on which the drug was first marketed
17 by any manufacturer and subparagraph (B) of
18 paragraph (3) shall be applied as if the term
19 ‘benchmark period CPI-U’ were defined under
20 subsection (h)(4) as if the reference to ‘January
21 2016’ under such subsection were a reference to
22 ‘January of the first year beginning after the
23 date on which the drug was first marketed by
24 any manufacturer’.

1 “(B) EXEMPTION FOR SHORTAGES.—The
2 Secretary may reduce or waive the rebate under
3 paragraph (1) with respect to a part D
4 rebtable drug that is described as currently in
5 shortage on the shortage list in effect under
6 section 506E of the Federal Food, Drug, and
7 Cosmetic Act or in the case of other exigent cir-
8 cumstances, as determined by the Secretary.

9 “(C) TREATMENT OF NEW FORMULA-
10 TIONS.—

11 “(i) IN GENERAL.—In the case of a
12 part D rebtable drug that is a line exten-
13 sion of a part D rebtable drug that is an
14 oral solid dosage form, the Secretary shall
15 establish a formula for determining the
16 amount specified in this subsection with
17 respect to such part D rebtable drug and
18 an applicable year with consideration of
19 the original part D rebtable drug.

20 “(ii) LINE EXTENSION DEFINED.—In
21 this subparagraph, the term ‘line exten-
22 sion’ means, with respect to a part D
23 rebtable drug, a new formulation of the
24 drug (as determined by the Secretary),
25 such as an extended release formulation,

1 but does not include an abuse-deterrent
2 formulation of the drug (as determined by
3 the Secretary), regardless of whether such
4 abuse-deterrent formulation is an extended
5 release formulation.

6 “(D) SELECTED DRUGS.—In the case of a
7 part D rebatable drug that is a selected drug
8 (as defined in section 1192(c)) for a price appli-
9 cability period (as defined in section
10 1191(b)(2))—

11 “(i) for plan years during such period
12 for which a maximum fair price (as defined
13 in section 1191(c)(2)) for such drug has
14 been determined and is applied under part
15 E of title XI, the rebate under subsection
16 (b)(1)(B) shall be waived; and

17 “(ii) in the case such drug is deter-
18 mined (pursuant to such section 1192(c))
19 to no longer be a selected drug, for each
20 applicable year beginning after the price
21 applicability period with respect to such
22 drug, subparagraphs (A) and (B) of para-
23 graph (4) shall be applied as if the term
24 ‘payment amount benchmark year’ were
25 defined under subsection (h)(3) as the last

1 year beginning during such price applica-
2 bility period with respect to such selected
3 drug and subparagraph (B) of paragraph
4 (3) shall be applied as if the term ‘bench-
5 mark period CPI-U’ were defined under
6 subsection (h)(4) as if the reference to
7 ‘January 2016’ under such subsection were
8 a reference to January of the last year be-
9 ginning during such price applicability pe-
10 riod with respect to such drug.

11 “(d) REBATE DEPOSITS.—Amounts paid as rebates
12 under subsection (c) shall be deposited into the Medicare
13 Prescription Drug Account in the Federal Supplementary
14 Medical Insurance Trust Fund established under section
15 1841.

16 “(e) INFORMATION.—For purposes of carrying out
17 this section, the Secretary shall use information submitted
18 by manufacturers under section 1927(b)(3).

19 “(f) CIVIL MONEY PENALTY.—In the case of a man-
20 ufacturer of a part D rebatable drug with an agreement
21 in effect under this section who has failed to comply with
22 the terms of the agreement under subsection (b)(1)(B)
23 with respect to such drug for an applicable year, the Sec-
24 retary may impose a civil money penalty on such manufac-
25 turer in an amount equal to 125 percent of the amount

1 specified in subsection (c) for such drug for such year.
2 The provisions of section 1128A (other than subsections
3 (a) (with respect to amounts of penalties or additional as-
4 sessments) and (b)) shall apply to a civil money penalty
5 under this subsection in the same manner as such provi-
6 sions apply to a penalty or proceeding under section
7 1128A(a).

8 “(g) JUDICIAL REVIEW.—There shall be no judicial
9 review of the following:

10 “(1) The determination of units under this sec-
11 tion.

12 “(2) The determination of whether a drug is a
13 part D rebatable drug under this section.

14 “(3) The calculation of the rebate amount
15 under this section.

16 “(h) DEFINITIONS.—In this section:

17 “(1) PART D REBATABLE DRUG DEFINED.—

18 “(A) IN GENERAL.—The term ‘part D
19 rebatable drug’ means a drug or biological that
20 would (without application of this section) be a
21 covered part D drug, except such term shall,
22 with respect to an applicable year, not include
23 such a drug or biological if the average annual
24 total cost under this part for such year per in-
25 dividual who uses such a drug or biological, as

1 determined by the Secretary, is less than, sub-
2 ject to subparagraph (B), \$100, as determined
3 by the Secretary using the most recent data
4 available or, if data is not available, as esti-
5 mated by the Secretary.

6 “(B) INCREASE.—The dollar amount ap-
7 plied under subparagraph (A)—

8 “(i) for 2026, shall be the dollar
9 amount specified under such subparagraph
10 for 2025, increased by the percentage in-
11 crease in the consumer price index for all
12 urban consumers (United States city aver-
13 age) for the 12-month period beginning
14 with January of 2025; and

15 “(ii) for a subsequent year, shall be
16 the dollar amount specified in this sub-
17 paragraph for the previous year, increased
18 by the percentage increase in the consumer
19 price index for all urban consumers
20 (United States city average) for the 12-
21 month period beginning with January of
22 the previous year.

23 Any dollar amount specified under this sub-
24 paragraph that is not a multiple of \$10 shall be
25 rounded to the nearest multiple of \$10.

1 “(2) UNIT DEFINED.—The term ‘unit’ means,
2 with respect to a part D rebatable drug, the lowest
3 identifiable quantity (such as a capsule or tablet,
4 milligram of molecules, or grams) of the part D
5 rebatable drug that is dispensed to individuals under
6 this part.

7 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—
8 The term ‘payment amount benchmark year’ means
9 the year beginning January 1, 2016.

10 “(4) BENCHMARK PERIOD CPI–U.—The term
11 ‘benchmark period CPI–U’ means the consumer
12 price index for all urban consumers (United States
13 city average) for January 2016.

14 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-
15 plicable year CPI–U’ means, with respect to an ap-
16 plicable year, the consumer price index for all urban
17 consumers (United States city average) for January
18 of such year.

19 “(6) AVERAGE MANUFACTURER PRICE.—The
20 term ‘average manufacturer price’ has the meaning,
21 with respect to a part D rebatable drug of a manu-
22 facturer, given such term in section 1927(k)(1), with
23 respect to a covered outpatient drug of a manufac-
24 turer for a rebate period under section 1927.”.

25 (b) CONFORMING AMENDMENTS.—

1 (1) TO PART B ASP CALCULATION.—Section
2 1847A(c)(3) of the Social Security Act (42 U.S.C.
3 1395w–3a(c)(3)), as amended by section 201(c)(1),
4 is further amended by striking “section 1927 or sec-
5 tion 1834(x)” and inserting “section 1927, section
6 1834(x), or section 1860D–14B”.

7 (2) EXCLUDING PART D DRUG INFLATION RE-
8 BATE FROM BEST PRICE.—Section
9 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
10 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
11 tion 201(c)(2), is further amended by striking “or
12 section 1834(x)” and inserting “, section 1834(x), or
13 section 1860D–14B”.

14 (3) COORDINATION WITH MEDICAID REBATE IN-
15 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
16 of the Social Security Act (42 U.S.C. 1396r–
17 8(b)(3)(D)(i)), as amended by section 201(c)(3), is
18 further amended by striking “or section 1834(x)”
19 and inserting “, section 1834(x), or section 1860D–
20 14B”.

21 **SEC. 214. PROHIBITING BRANDING ON PART D BENEFIT**
22 **CARDS.**

23 (a) IN GENERAL.—Section 1851(j)(2)(B) of the So-
24 cial Security Act (42 U.S.C. 1395w–21(j)(2)(B)) is
25 amended by striking “co-branded network provider” and

1 inserting “co-branded, co-owned, or affiliated network pro-
2 vider, pharmacy, or pharmacy benefit manager”.

3 (b) **EFFECTIVE DATE.**—The amendment made by
4 subsection (a) shall apply to plan years beginning on or
5 after January 1, 2025.

6 **SEC. 215. REQUIRING PRESCRIPTION DRUG PLANS AND**
7 **MA-PD PLANS TO REPORT POTENTIAL**
8 **FRAUD, WASTE, AND ABUSE TO THE SEC-**
9 **RETARY OF HHS.**

10 Section 1860D–4 of the Social Security Act (42
11 U.S.C. 1395w–104), as amended by section 225, is
12 amended by adding at the end the following new sub-
13 section:

14 “(p) **REPORTING POTENTIAL FRAUD, WASTE, AND**
15 **ABUSE.**—Beginning January 1, 2024, the PDP sponsor
16 of a prescription drug plan shall report to the Secretary,
17 as specified by the Secretary—

18 “(1) any substantiated or suspicious activities
19 (as defined by the Secretary) with respect to the
20 program under this part as it relates to fraud,
21 waste, and abuse; and

22 “(2) any steps made by the PDP sponsor after
23 identifying such activities to take corrective ac-
24 tions.”.

1 **SEC. 216. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
2 **URES UNDER MEDICARE PART D.**

3 Section 1860D–4(c) of the Social Security Act (42
4 U.S.C. 1395w–104(c)), as amended by section 226, is
5 amended by adding at the end the following new para-
6 graph:

7 “(8) APPLICATION OF PHARMACY QUALITY
8 MEASURES.—

9 “(A) IN GENERAL.—A PDP sponsor that
10 implements incentive payments to a pharmacy
11 or price concessions paid by a pharmacy based
12 on quality measures shall use measures estab-
13 lished or approved by the Secretary under sub-
14 paragraph (B) with respect to payment for cov-
15 ered part D drugs dispensed by such pharmacy.

16 “(B) STANDARD PHARMACY QUALITY
17 MEASURES.—The Secretary shall establish or
18 approve standard quality measures from a con-
19 sensus and evidence-based organization for pay-
20 ments described in subparagraph (A). Such
21 measures shall focus on patient health outcomes
22 and be based on proven criteria measuring
23 pharmacy performance.

24 “(C) EFFECTIVE DATE.—The requirement
25 under subparagraph (A) shall take effect for
26 plan years beginning on or after January 1,

1 2026, or such earlier date specified by the Sec-
2 retary if the Secretary determines there are suf-
3 ficient measures established or approved under
4 subparagraph (B) to meet the requirement
5 under subparagraph (A).”.

6 **SEC. 217. ADDITION OF NEW MEASURES BASED ON ACCESS**
7 **TO BIOSIMILAR BIOLOGICAL PRODUCTS TO**
8 **THE 5-STAR RATING SYSTEM UNDER MEDI-**
9 **CARE ADVANTAGE.**

10 (a) IN GENERAL.—Section 1853(o)(4) of the Social
11 Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by
12 adding at the end the following new subparagraph:

13 “(E) ADDITION OF NEW MEASURES BASED
14 ON ACCESS TO BIOSIMILAR BIOLOGICAL PROD-
15 UCTS.—

16 “(i) IN GENERAL.—For 2028 and
17 subsequent years, the Secretary shall add a
18 new set of measures to the 5-star rating
19 system based on access to biosimilar bio-
20 logical products covered under part B and,
21 in the case of MA–PD plans, such prod-
22 ucts that are covered part D drugs. Such
23 measures shall assess the impact a plan’s
24 benefit structure may have on enrollees’
25 utilization of or ability to access biosimilar

1 biological products, including in compari-
2 son to the reference biological product, and
3 shall include measures, as applicable, with
4 respect to the following:

5 “(I) COVERAGE.—Assessing
6 whether a biosimilar biological prod-
7 uct is on the plan formulary in lieu of
8 or in addition to the reference biologi-
9 cal product.

10 “(II) PREFERENCING.—Assess-
11 ing tier placement or cost-sharing for
12 a biosimilar biological product relative
13 to the reference biological product.

14 “(III) UTILIZATION MANAGE-
15 MENT TOOLS.—Assessing whether and
16 how utilization management tools are
17 used with respect to a biosimilar bio-
18 logical product relative to the ref-
19 erence biological product.

20 “(IV) UTILIZATION.—Assessing
21 the percentage of enrollees prescribed
22 the biosimilar biological product and
23 the percentage of enrollees prescribed
24 the reference biological product when

1 the reference biological product is also
2 on the plan formulary.

3 “(ii) DEFINITIONS.—In this subpara-
4 graph, the terms ‘biosimilar biological
5 product’ and ‘reference biological product’
6 have the meaning given those terms in sec-
7 tion 1847A(c)(6).

8 “(iii) PROTECTING PATIENT INTER-
9 ESTS.—In developing such measures, the
10 Secretary shall ensure that each measure
11 developed to address coverage,
12 preferencing, or utilization management is
13 constructed such that patients retain ac-
14 cess to appropriate therapeutic options
15 without undue administrative burden.”.

16 (b) CLARIFICATION REGARDING APPLICATION TO
17 PRESCRIPTION DRUG PLANS.—To the extent the Sec-
18 retary of Health and Human Services applies the 5-star
19 rating system under section 1853(o)(4) of the Social Secu-
20 rity Act (42 U.S.C. 1395w–23(o)(4)), or a similar system,
21 to prescription drug plans under part D of title XVIII of
22 such Act, the provisions of subparagraph (E) of such sec-
23 tion, as added by subsection (a) of this section, shall apply
24 under the system with respect to such plans in the same

1 manner as such provisions apply to the 5-star rating sys-
2 tem under such section 1853(o)(4).

3 **SEC. 218. HHS STUDY AND REPORT ON THE INFLUENCE OF**
4 **PHARMACEUTICAL MANUFACTURER THIRD-**
5 **PARTY REIMBURSEMENT HUBS ON HEALTH**
6 **CARE PROVIDERS WHO PRESCRIBE THEIR**
7 **DRUGS AND BIOLOGICALS.**

8 (a) STUDY.—

9 (1) IN GENERAL.—The Secretary of Health and
10 Human Services (in this section referred to as the
11 “Secretary”) shall conduct a study on the influence
12 of pharmaceutical manufacturer distribution models
13 that provide third-party reimbursement hub services
14 on health care providers who prescribe the manufac-
15 turer’s drugs and biologicals, including for Medicare
16 part D beneficiaries.

17 (2) REQUIREMENTS.—The study under para-
18 graph (1) shall include an analysis of the following:

19 (A) The influence of pharmaceutical manu-
20 facturer distribution models that provide third-
21 party reimbursement hub services to health care
22 providers who prescribe the manufacturer’s
23 drugs and biologicals, including—

24 (i) the operations of pharmaceutical
25 manufacturer distribution models that pro-

1 vide reimbursement hub services for health
2 care providers who prescribe the manufac-
3 turer's products;

4 (ii) Federal laws affecting these phar-
5 maceutical manufacturer distribution mod-
6 els; and

7 (iii) whether hub services could im-
8 properly incentivize health care providers
9 to deem a drug or biological as medically
10 necessary under section 423.578 of title
11 42, Code of Federal Regulations.

12 (B) Other areas determined appropriate by
13 the Secretary.

14 (b) REPORT.—Not later than January 1, 2024, the
15 Secretary shall submit to Congress a report on the study
16 conducted under subsection (a), together with rec-
17 ommendations for such legislation and administrative ac-
18 tion as the Secretary determines appropriate.

19 (c) CONSULTATION.—In conducting the study under
20 subsection (a) and preparing the report under subsection
21 (b), the Secretary shall consult with the Attorney General.

1 **SEC. 219. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**
2 **INCURRED COSTS FOR INSULIN PRODUCTS**
3 **AND SUPPLIES UNDER A PRESCRIPTION**
4 **DRUG PLAN OR MA-PD PLAN.**

5 (a) IN GENERAL.—Section 1860D–2 of the Social
6 Security Act (42 U.S.C. 1395w–102), as amended by sec-
7 tions 121 and 133, is further amended—

8 (1) in subsection (b)(2)—

9 (A) in subparagraph (A), by striking “and
10 (E)” and inserting “(E), and (F)”;

11 (B) in subparagraph (B), by striking “and
12 (D)” and inserting “(D), and (F)”;

13 (C) by adding at the end the following new
14 subparagraph:

15 “(F) CAP ON INCURRED COSTS FOR INSU-
16 LIN PRODUCTS AND SUPPLIES.—

17 “(i) IN GENERAL.—The coverage pro-
18 vides benefits, for costs above the annual
19 deductible specified in paragraph (1) and
20 up to the annual out-of-pocket threshold
21 described in paragraph (4)(B) and with re-
22 spect to a month (beginning with January
23 of 2022), with cost sharing that is equal to
24 \$0 for a specified covered part D drug (as
25 defined in clause (iii)) furnished to an indi-
26 vidual who has incurred costs during such

1 month with respect to specified covered
2 part D drugs equal to—

3 “(I) for months occurring in
4 2022, \$50; or

5 “(II) for months occurring in a
6 subsequent year, the amount applica-
7 ble under this clause for months oc-
8 ccurring in the year preceding such
9 subsequent year, increased by the an-
10 nual percentage increase specified in
11 paragraph (6) for such subsequent
12 year and rounded to the nearest dol-
13 lar.

14 “(ii) APPLICATION.—The provisions
15 of clauses (i) through (iii) of paragraph
16 (4)(C) shall apply with respect to the de-
17 termination of the incurred costs for speci-
18 fied covered part D drugs for purposes of
19 clause (i) in the same manner as such pro-
20 visions apply with respect to the deter-
21 mination of incurred costs for covered part
22 D drugs for purposes of paragraph (4)(A).

23 “(iii) SPECIFIED COVERED PART D
24 DRUG.—For purposes of this subpara-
25 graph, the term ‘specified covered part D

1 drug’ means a covered part D drug that
2 is—

3 “(I) insulin; or

4 “(II) a medical supply associated
5 with the injection of insulin (as de-
6 fined in regulations of the Secretary
7 promulgated pursuant to subsection
8 (e)(1)(B)).”; and

9 (2) in subsection (c), by adding at the end the
10 following new paragraph:

11 “(5) SAME PROTECTION WITH RESPECT TO EX-
12 PENDITURES FOR INSULIN AND CERTAIN MEDICAL
13 SUPPLIES.—The coverage provides the coverage re-
14 quired under subsection (b)(2)(F).”.

15 (b) CONFORMING AMENDMENTS.—

16 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)
17 of the Social Security Act (42 U.S.C. 1395w–
18 114(a)(1)(D)), as amended by section 121, is fur-
19 ther amended—

20 (A) in clause (ii), by striking “section
21 1860D–2(b)(2)” and inserting “section 1860D–
22 2(b)(2)(A)”; and

23 (B) in clause (iii), by striking “section
24 1860D–2(b)(2)” and inserting “section 1860D–
25 2(b)(2)(A)”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by paragraph (1) shall apply with respect to plan
3 year 2022 and each subsequent plan year.

4 **SEC. 220. MONTHLY OUT-OF-POCKET COST SHARING MAX-**
5 **IMUM FOR ENROLLEES WHO INCUR A SIG-**
6 **NIFICANT PORTION OF COSTS TOWARDS AN-**
7 **NUAL OUT-OF-POCKET THRESHOLD.**

8 (a) IN GENERAL.—Section 1860D–2(b) of the Social
9 Security Act (42 U.S.C. 1395w–102(b)), as amended by
10 section 2, is amended—

11 (1) in paragraph (2)—

12 (A) in subparagraph (A), by striking “and
13 (D)” and inserting “, (D), and (E)”; and

14 (B) by adding at the end the following new
15 subparagraph:

16 “(E) MONTHLY OUT-OF-POCKET COST
17 SHARING MAXIMUM FOR ENROLLEES WHO
18 INCUR A SIGNIFICANT PORTION OF COSTS TO-
19 WARDS ANNUAL OUT-OF-POCKET THRESH-
20 OLD.—

21 “(i) ESTABLISHMENT OF PROCESS.—

22 “(I) IN GENERAL.—For plan
23 years beginning on or after January
24 1, 2024, the Secretary shall, through
25 notice and comment rulemaking, es-

1 establish a process under which each
2 PDP sponsor offering a prescription
3 drug plan and each MA organization
4 offering an MA–PD plan shall each
5 plan year automatically enroll applica-
6 ble enrollees in the option to have
7 their monthly out-of-pocket cost-shar-
8 ing under the plan capped and paid in
9 monthly installments in accordance
10 with this subparagraph (referred to in
11 this subparagraph as the ‘monthly
12 out-of-pocket cost sharing maximum
13 option’).

14 “(II) OPT OUT.—The process es-
15 tablished under this clause shall per-
16 mit an applicable enrollee, prior to the
17 beginning of the plan year or at any
18 point during the plan year, to opt out
19 of enrollment in the monthly out-of-
20 pocket cost sharing maximum option
21 and pay any out-of-pocket cost-shar-
22 ing otherwise applicable for any cov-
23 ered part D drug in full at the time
24 of the dispensing of such drug (or at
25 the time of such opt out in the case

1 of costs incurred during such enroll-
2 ment that have not yet been billed to
3 the enrollee).

4 “(ii) DEFINITIONS.—

5 “(I) APPLICABLE ENROLLEE.—

6 In this subparagraph, the term ‘appli-
7 cable enrollee’ means any enrollee in a
8 prescription drug plan or an MA–PD
9 plan, including an enrollee who is a
10 subsidy eligible individual (as defined
11 in paragraph (3) of section 1860D–
12 14(a)), who incurs or is likely to incur
13 a significant percentage of costs for
14 covered part D drugs.

15 “(II) SIGNIFICANT PERCENT-

16 AGE.—For purposes of subclause (I),
17 the Secretary shall, in the rulemaking
18 under clause (i), define the term ‘sig-
19 nificant percentage’ with respect to a
20 percentage of the annual out-of-pocket
21 threshold specified in paragraph
22 (4)(B) but in no case shall the ‘sig-
23 nificant percentage’ be less than 50
24 percent or more than 100 percent of
25 the annual out-of-pocket threshold.

1 “(iii) DETERMINATION OF MONTHLY
2 OUT-OF-POCKET COST SHARING MAX-
3 IMUM.—For each month in a plan year in
4 which an applicable enrollee is enrolled in
5 the monthly out-of-pocket cost sharing
6 maximum option, the PDP sponsor or MA
7 organization shall determine a monthly
8 out-of-pocket cost sharing maximum (as
9 defined in clause (v)) for such enrollee.

10 “(iv) BENEFICIARY MONTHLY PAY-
11 MENTS.—With respect to an applicable en-
12 rollee who is enrolled in the monthly out-
13 of-pocket cost sharing maximum option,
14 for each month described in clause (iii),
15 the PDP sponsor or MA organization shall
16 bill such enrollee an amount (not to exceed
17 the monthly out-of-pocket cost sharing
18 maximum) for the out-of-pocket costs of
19 such enrollee in such month.

20 “(v) MONTHLY OUT-OF-POCKET COST
21 SHARING MAXIMUM DEFINED.—In this
22 subparagraph, the term ‘monthly out-of-
23 pocket cost sharing maximum’ means, with
24 respect to an enrollee—

1 “(I) for the first month in which
2 this subparagraph applies, an amount
3 determined by calculating—

4 “(aa) the annual out-of-
5 pocket threshold specified in
6 paragraph (4)(B) minus the in-
7 curred costs of the enrollee as de-
8 scribed in paragraph (4)(C); di-
9 vided by

10 “(bb) the number of months
11 remaining in the plan year; and

12 “(II) for a subsequent month, an
13 amount determined by calculating—

14 “(aa) the sum of any re-
15 maining out-of-pocket costs owed
16 by the enrollee from a previous
17 month that have not yet been
18 billed to the enrollee and any ad-
19 ditional costs incurred by the en-
20 rollee; divided by

21 “(bb) the number of months
22 remaining in the plan year.

23 “(vi) ADDITIONAL REQUIREMENTS.—

24 The following requirements shall apply
25 with respect to the monthly out-of-pocket

1 cost sharing maximum option under this
2 subparagraph:

3 “(I) SECRETARIAL RESPONSIBIL-
4 ITIES.—The Secretary shall provide
5 information to part D eligible individ-
6 uals on the monthly out-of-pocket cost
7 sharing maximum option through edu-
8 cational materials, including through
9 the notices provided under section
10 1804(a).

11 “(II) PDP SPONSOR AND MA OR-
12 GANIZATION RESPONSIBILITIES.—
13 Each PDP sponsor offering a pre-
14 scription drug plan or MA organiza-
15 tion offering an MA–PD plan—

16 “(aa) shall not limit the ap-
17 plication of the monthly out-of-
18 pocket cost sharing maximum op-
19 tion to certain covered part D
20 drugs;

21 “(bb) shall, prior to the plan
22 year, notify prospective enrollees
23 of such option, including the
24 availability of the opt out under
25 clause (i)(II);

1 “(cc) shall include informa-
2 tion on such option in enrollee
3 educational materials, including
4 the availability of the opt out
5 under clause (i)(II);

6 “(dd) shall have in place a
7 mechanism to notify a pharmacy
8 during the plan year when an en-
9 rollee incurs out-of-pocket costs
10 with respect to covered part D
11 drugs that make it likely the en-
12 rollee is an applicable enrollee;

13 “(ee) shall provide that a
14 pharmacy, after receiving a noti-
15 fication described in item (dd)
16 with respect to an enrollee, in-
17 forms the enrollee of such notifi-
18 cation;

19 “(ff) shall ensure that the
20 application of this subparagraph
21 has no effect on the amount paid
22 to pharmacies (or the timing of
23 such payments) with respect to
24 covered part D drugs dispensed
25 to the enrollee; and

1 “(gg) shall have in place a
2 financial reconciliation process to
3 correct inaccuracies in payments
4 made by an enrollee under this
5 subparagraph with respect to
6 covered part D drugs during the
7 plan year.

8 “(III) FAILURE TO PAY AMOUNT
9 BILLED UNDER MONTHLY OUT-OF-
10 POCKET COST SHARING MAXIMUM OP-
11 TION.—If an applicable enrollee fails
12 to pay the amount billed for a month
13 as required under this subparagraph,
14 the applicable enrollee’s enrollment in
15 the monthly out-of-pocket cost sharing
16 maximum option shall be terminated
17 and the enrollee shall pay the cost-
18 sharing otherwise applicable for any
19 covered part D drugs subsequently
20 dispensed to the enrollee up to the an-
21 nual out-of-pocket threshold specified
22 in paragraph (4)(B).

23 “(IV) CLARIFICATION REGARD-
24 ING PAST DUE AMOUNTS.—Nothing in
25 this subparagraph shall be construed

1 as prohibiting a PDP sponsor or an
2 MA organization from billing an en-
3 rollee for an amount owed under this
4 subparagraph.

5 “(V) TREATMENT OF UNSET-
6 TLED BALANCES.—Any unsettled bal-
7 ances with respect to amounts owed
8 under this subparagraph shall be
9 treated as plan losses and the Sec-
10 retary shall not be liable for any such
11 balances outside of those assumed as
12 losses estimated in plan bids.”; and

13 (2) in paragraph (4)—

14 (A) in subparagraph (C), by striking “and
15 subject to subparagraph (F)” and inserting
16 “and subject to subparagraphs (F) and (G)”;
17 and

18 (B) by adding at the end the following new
19 subparagraph:

20 “(G) INCLUSION OF COSTS PAID UNDER
21 MONTHLY OUT-OF-POCKET COST SHARING MAX-
22 IMUM OPTION.—In applying subparagraph (A),
23 with respect to an applicable enrollee who is en-
24 rolled in the monthly out-of-pocket cost sharing
25 maximum option described in clause (i)(I) of

1 paragraph (2)(E), costs shall be treated as in-
2 curred if such costs are paid by a PDP sponsor
3 or an MA organization under the process pro-
4 vided under such paragraph.”.

5 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
6 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
7 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
8 ing at the end the following new paragraph:

9 “(4) SAME MONTHLY OUT-OF-POCKET COST
10 SHARING MAXIMUM.—For plan years beginning on
11 or after January 1, 2024, the monthly out-of-pocket
12 cost sharing maximum for applicable enrollees under
13 the process provided under subsection (b)(2)(E)
14 shall apply to such coverage.”.

15 **Subtitle C—Miscellaneous**

16 **SEC. 220. DRUG MANUFACTURER PRICE TRANSPARENCY.**

17 Title XI of the Social Security Act (42 U.S.C. 1301
18 et seq.) is amended by inserting after section 1128K the
19 following new section:

20 **“SEC. 1128L. DRUG MANUFACTURER PRICE TRANS-** 21 **PARENCY.**

22 “(a) IN GENERAL.—

23 “(1) DETERMINATIONS.—Beginning July 1,
24 2025, the Secretary shall make determinations as to

1 whether a drug is an applicable drug as described in
2 subsection (b).

3 “(2) REQUIRED JUSTIFICATION.—If the Sec-
4 retary determines under paragraph (1) that an ap-
5 plicable drug is described in subsection (b), the man-
6 ufacturer of the applicable drug shall submit to the
7 Secretary the justification described in subsection (c)
8 in accordance with the timing described in sub-
9 section (d).

10 “(b) APPLICABLE DRUG DESCRIBED.—

11 “(1) IN GENERAL.—An applicable drug is de-
12 scribed in this subsection if it meets any of the fol-
13 lowing at the time of the determination:

14 “(A) LARGE INCREASE.—The drug (per
15 dose)—

16 “(i) has a wholesale acquisition cost of
17 at least \$10; and

18 “(ii) had an increase in the wholesale
19 acquisition cost, with respect to determina-
20 tions made—

21 “(I) during 2023, of at least 100
22 percent since the date of the enact-
23 ment of this section;

24 “(II) during 2024, of at least
25 100 percent in the preceding 12

1 months or of at least 150 percent in
2 the preceding 24 months;

3 “(III) during 2025, of at least
4 100 percent in the preceding 12
5 months or of at least 200 percent in
6 the preceding 36 months;

7 “(IV) during 2026, of at least
8 100 percent in the preceding 12
9 months or of at least 250 percent in
10 the preceding 48 months; or

11 “(V) on or after January 1,
12 2027, of at least 100 percent in the
13 preceding 12 months or of at least
14 300 percent in the preceding 60
15 months.

16 “(B) HIGH SPENDING WITH INCREASE.—

17 The drug—

18 “(i) was in the top 50th percentile of
19 net spending under title XVIII or XIX (to
20 the extent data is available) during any 12-
21 month period in the preceding 60 months;
22 and

23 “(ii) per dose, had an increase in the
24 wholesale acquisition cost, with respect to
25 determinations made—

1 “(I) during 2023, of at least 15
2 percent since the date of the enact-
3 ment of this section;

4 “(II) during 2024, of at least 15
5 percent in the preceding 12 months or
6 of at least 20 percent in the preceding
7 24 months;

8 “(III) during 2025, of at least 15
9 percent in the preceding 12 months or
10 of at least 30 percent in the preceding
11 36 months;

12 “(IV) during 2026, of at least 15
13 percent in the preceding 12 months or
14 of at least 40 percent in the preceding
15 48 months; or

16 “(V) on or after January 1,
17 2027, of at least 15 percent in the
18 preceding 12 months or of at least 50
19 percent in the preceding 60 months.

20 “(C) HIGH LAUNCH PRICE FOR NEW
21 DRUGS.—In the case of a drug that is marketed
22 for the first time on or after January 1, 2023,
23 and for which the manufacturer has established
24 the first wholesale acquisition cost on or after
25 such date, such wholesale acquisition cost for a

1 year's supply or a course of treatment for such
2 drug exceeds the gross spending for covered
3 part D drugs at which the annual out-of-pocket
4 threshold under section 1860D-2(b)(4)(B)
5 would be met for the year.

6 “(2) SPECIAL RULES.—

7 “(A) AUTHORITY OF SECRETARY TO SUB-
8 STITUTE PERCENTAGES WITHIN A DE MINIMIS
9 RANGE.—For purposes of applying paragraph
10 (1), the Secretary may substitute for each per-
11 centage described in subparagraph (A) or (B)
12 of such paragraph (other than the percentile de-
13 scribed subparagraph (B)(i) of such paragraph)
14 a percentage within a de minimis range speci-
15 fied by the Secretary below the percentage so
16 described.

17 “(B) DRUGS WITH HIGH LAUNCH PRICES
18 ANNUALLY REPORT UNTIL A THERAPEUTIC
19 EQUIVALENT IS AVAILABLE.—In the case of a
20 drug that the Secretary determines is an appli-
21 cable drug described in subparagraph (C) of
22 paragraph (1), such drug shall remain de-
23 scribed in such subparagraph (C) (and the
24 manufacturer of such drug shall annually re-
25 port the justification under subsection (c)(2))

1 until the Secretary determines that there is a
2 therapeutic equivalent (as defined in section
3 314.3 of title 21, Code of Federal Regulations,
4 or any successor regulation) for such drug.

5 “(3) DOSE.—For purposes of applying para-
6 graph (1), the Secretary shall establish a definition
7 of the term ‘dose’.

8 “(c) JUSTIFICATION DESCRIBED.—

9 “(1) INCREASE IN WAC.—In the case of a drug
10 that the Secretary determines is an applicable drug
11 described in subparagraph (A) or (B) of subsection
12 (b)(1), the justification described in this subsection
13 is all relevant, truthful, and nonmisleading informa-
14 tion and supporting documentation necessary to jus-
15 tify the increase in the wholesale acquisition cost of
16 the applicable drug of the manufacturer, as deter-
17 mined appropriate by the Secretary and which may
18 include the following:

19 “(A) The individual factors that have con-
20 tributed to the increase in the wholesale acqui-
21 sition cost.

22 “(B) An explanation of the role of each
23 factor in contributing to such increase.

24 “(C) Total expenditures of the manufac-
25 turer on—

1 “(i) materials and manufacturing for
2 such drug;

3 “(ii) acquiring patents and licensing
4 for each drug of the manufacturer; and

5 “(iii) costs to purchase or acquire the
6 drug from another company, if applicable.

7 “(D) The percentage of total expenditures
8 of the manufacturer on research and develop-
9 ment for such drug that was derived from Fed-
10 eral funds.

11 “(E) The total expenditures of the manu-
12 facturer on research and development for such
13 drug.

14 “(F) The total revenue and net profit gen-
15 erated from the applicable drug for each cal-
16 endar year since drug approval.

17 “(G) The total expenditures of the manu-
18 facturer that are associated with marketing and
19 advertising for the applicable drug.

20 “(H) Additional information specific to the
21 manufacturer of the applicable drug, such as—

22 “(i) the total revenue and net profit of
23 the manufacturer for the period of such in-
24 crease, as determined by the Secretary;

1 “(ii) metrics used to determine execu-
2 tive compensation;

3 “(iii) any additional information re-
4 lated to drug pricing decisions of the man-
5 ufacturer, such as total expenditures on—

6 “(I) drug research and develop-
7 ment; or

8 “(II) clinical trials on drugs that
9 failed to receive approval by the Food
10 and Drug Administration.

11 “(2) HIGH LAUNCH PRICE.—In the case of a
12 drug that the Secretary determines is an applicable
13 drug described in subparagraph (C) of subsection
14 (b)(1), the justification described in this subsection
15 is all relevant, truthful, and nonmisleading informa-
16 tion and supporting documentation necessary to jus-
17 tify the wholesale acquisition cost of the applicable
18 drug of the manufacturer, as determined by the Sec-
19 retary and which may include the items described in
20 subparagraph (C) through (H) of paragraph (1).

21 “(d) TIMING.—

22 “(1) NOTIFICATION.—Not later than 60 days
23 after the date on which the Secretary makes the de-
24 termination that a drug is an applicable drug under
25 subsection (b), the Secretary shall notify the manu-

1 factorer of the applicable drug of such determina-
2 tion.

3 “(2) SUBMISSION OF JUSTIFICATION.—Not
4 later than 180 days after the date on which a manu-
5 facturer receives a notification under paragraph (1),
6 the manufacturer shall submit to the Secretary the
7 justification required under subsection (a).

8 “(3) POSTING ON INTERNET WEBSITE.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), not later than 30 days after receiv-
11 ing the justification under paragraph (2), the
12 Secretary shall post on the Internet website of
13 the Centers for Medicare & Medicaid Services
14 the justification, together with a summary of
15 such justification that is written and formatted
16 using language that is easily understandable by
17 beneficiaries under titles XVIII and XIX.

18 “(B) EXCLUSION OF PROPRIETARY INFOR-
19 MATION.—The Secretary shall exclude propri-
20 etary information, such as trade secrets and in-
21 tellectual property, submitted by the manufac-
22 turer in the justification under paragraph (2)
23 from the posting described in subparagraph
24 (A).

1 “(e) EXCEPTION TO REQUIREMENT FOR SUBMIS-
2 SION.—In the case of a drug that the Secretary deter-
3 mines is an applicable drug described in subparagraph (A)
4 or (B) of subsection (b)(1), the requirement to submit a
5 justification under subsection (a) shall not apply where the
6 manufacturer, after receiving the notification under sub-
7 section (d)(1) with respect to the applicable drug of the
8 manufacturer, reduces the wholesale acquisition cost of a
9 drug so that it no longer is described in such subpara-
10 graph (A) or (B) for at least a 4-month period, as deter-
11 mined by the Secretary.

12 “(f) PENALTIES.—

13 “(1) FAILURE TO SUBMIT TIMELY JUSTIFICA-
14 TION.—If the Secretary determines that a manufac-
15 turer has failed to submit a justification as required
16 under this section, including in accordance with the
17 timing and form required, with respect to an appli-
18 cable drug, the Secretary shall apply a civil mone-
19 tary penalty in an amount of \$10,000 for each day
20 the manufacturer has failed to submit such justifica-
21 tion as so required.

22 “(2) FALSE INFORMATION.—Any manufacturer
23 that submits a justification under this section and
24 knowingly provides false information in such jus-
25 tification is subject to a civil monetary penalty in an

1 amount not to exceed \$100,000 for each item of
2 false information.

3 “(3) APPLICATION OF PROCEDURES.—The pro-
4 visions of section 1128A (other than subsections (a)
5 and (b)) shall apply to a civil monetary penalty
6 under this subsection in the same manner as such
7 provisions apply to a penalty or proceeding under
8 section 1128A(a). Civil monetary penalties imposed
9 under this subsection are in addition to other pen-
10 alties as may be prescribed by law.

11 “(g) DEFINITIONS.—In this section:

12 “(1) DRUG.—The term ‘drug’ means a drug, as
13 defined in section 201(g) of the Federal Food, Drug,
14 and Cosmetic Act, that is intended for human use
15 and subject to section 503(b)(1) of such Act, includ-
16 ing a product licensed under section 351 of the Pub-
17 lic health Service Act.

18 “(2) MANUFACTURER.—The term ‘manufac-
19 turer’ has the meaning given that term in section
20 1847A(c)(6)(A).

21 “(3) WHOLESALE ACQUISITION COST.—The
22 term ‘wholesale acquisition cost’ has the meaning
23 given that term in section 1847A(c)(6)(B).”.

1 **SEC. 221. STRENGTHENING AND EXPANDING PHARMACY**
2 **BENEFIT MANAGERS TRANSPARENCY RE-**
3 **QUIREMENTS.**

4 Section 1150A of the Social Security Act (42 U.S.C.
5 1320b–23), as amended by section 223, is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1), by striking “or” at
8 then end;

9 (B) in paragraph (2), by striking the
10 comma at the end and inserting “; or”; and

11 (C) by inserting after paragraph (2) the
12 following new paragraph:

13 “(3) a State plan under title XIX, including a
14 managed care entity (as defined in section
15 1932(a)(1)(B)),”;

16 (2) in subsection (b)—

17 (A) in paragraph (2)—

18 (i) by striking “(excluding bona fide”
19 and all that follows through “patient edu-
20 cation programs))”; and

21 (ii) by striking “aggregate amount of”
22 and inserting “aggregate amount and per-
23 centage of”;

24 (B) in paragraph (3), by striking “aggre-
25 gate amount of” and inserting “aggregate

1 amount and percentage (defined as a share of
2 gross drug costs) of”; and

3 (C) by adding at the end the following new
4 paragraph:

5 “(4) The aggregate amount of bona fide service
6 fees (which include distribution service fees, inven-
7 tory management fees, product stocking allowances,
8 and fees associated with administrative services
9 agreements and patient care programs (such as
10 medication compliance programs and patient edu-
11 cation programs)) the PBM received from—

12 “(A) PDP sponsors;

13 “(B) qualified health benefit plans;

14 “(C) managed care entities (as defined in
15 section 1932(a)(1)(b)); and

16 “(D) drug manufacturers.”;

17 (3) in subsection (c), by adding at the end the
18 following new paragraphs:

19 “(5) To States to carry out their administration
20 and oversight of the State plan under title XIX.

21 “(6) To the Federal Trade Commission to carry
22 out section 5(a) of the Federal Trade Commission
23 Act (15 U.S.C. 45a) and any other relevant con-
24 sumer protection or antitrust authorities enforced by

1 such Commission, including reviewing proposed
2 mergers in the prescription drug sector.

3 “(7) To assist the Department of Justice to
4 carry out its antitrust authorities, including review-
5 ing proposed mergers in the prescription drug sec-
6 tor.”; and

7 (4) by adding at the end the following new sub-
8 section:

9 “(f) ANNUAL OIG EVALUATION AND REPORT.—

10 “(1) ANALYSIS.—The Inspector General of the
11 Department of Health and Human Services shall
12 conduct an annual evaluation of the information pro-
13 vided to the Secretary under this section. Such eval-
14 uation shall include an analysis of—

15 “(A) PBM rebates;

16 “(B) administrative fees;

17 “(C) the difference between what plans pay
18 PBMs and what PBMs pay pharmacies;

19 “(D) generic dispensing rates; and

20 “(E) other areas determined appropriate
21 by the Inspector General.

22 “(2) REPORT.—Not later than July 1, 2023,
23 and annually thereafter, the Inspector General of the
24 Department of Health and Human Services shall
25 submit to Congress a report containing the results

1 of the evaluation conducted under paragraph (1), to-
2 gether with recommendations for such legislation
3 and administrative action as the Inspector General
4 determines appropriate. Such report shall not dis-
5 close the identity of a specific PBM, plan, or price
6 charged for a drug.”.

7 **SEC. 222. PRESCRIPTION DRUG PRICING DASHBOARDS.**

8 Part A of title XI of the Social Security Act is
9 amended by adding at the end the following new section:

10 **“SEC. 1150C. PRESCRIPTION DRUG PRICING DASHBOARDS.**

11 “(a) IN GENERAL.—Beginning not later than Janu-
12 ary 1, 2023, the Secretary shall establish, and annually
13 update, internet website-based dashboards, through which
14 beneficiaries, clinicians, researchers, and the public can re-
15 view information on spending for, and utilization of, pre-
16 scription drugs and biologicals (and related supplies and
17 mechanisms of delivery) covered under each of parts B
18 and D of title XVIII and under a State program under
19 title XIX, including information on trends of such spend-
20 ing and utilization over time.

21 “(b) MEDICARE PART B DRUG AND BIOLOGICAL
22 DASHBOARD.—

23 “(1) IN GENERAL.—The dashboard established
24 under subsection (a) for part B of title XVIII shall
25 provide the information described in paragraph (2).

1 “(2) INFORMATION DESCRIBED.—The informa-
2 tion described in this paragraph is the following in-
3 formation with respect to drug or biologicals covered
4 under such part B:

5 “(A) The brand name and, if applicable,
6 the generic names of the drug or biological.

7 “(B) Consumer-friendly information on the
8 uses and clinical indications of the drug or bio-
9 logical.

10 “(C) The manufacturer or labeler of the
11 drug or biological.

12 “(D) To the extent feasible, the following
13 information:

14 “(i) Average total spending per dos-
15 age unit of the drug or biological in the
16 most recent 2 calendar years for which
17 data is available.

18 “(ii) The percentage change in aver-
19 age spending on the drug or biological per
20 dosage unit between the most recent cal-
21 endar year for which data is available
22 and—

23 “(I) the preceding calendar year;
24 and

1 “(II) the preceding 5 and 10 cal-
2 endar years.

3 “(iii) The annual growth rate in aver-
4 age spending per dosage unit of the drug
5 or biological in the most recent 5 or 10
6 calendar years for which data is available.

7 “(iv) Total spending for the drug or
8 biological for the most recent calendar year
9 for which data is available.

10 “(v) The number of beneficiaries re-
11 ceiving the drug or biological in the most
12 recent calendar year for which data is
13 available.

14 “(vi) Average spending on the drug
15 per beneficiary for the most recent cal-
16 endar year for which data is available.

17 “(E) The average sales price of the drug
18 or biological (as determined under section
19 1847A) for the most recent quarter.

20 “(F) Consumer-friendly information about
21 the coinsurance amount for the drug or biologi-
22 cal for beneficiaries for the most recent quarter.
23 Such information shall not include coinsurance
24 amounts for qualified medicare beneficiaries (as
25 defined in section 1905(p)(1)).

1 “(G) For the most recent calendar year for
2 which data is available—

3 “(i) the 15 drugs and biologicals with
4 the highest total spending under such part;
5 and

6 “(ii) any drug or biological for which
7 the average annual per beneficiary spend-
8 ing exceeds the gross spending for covered
9 part D drugs at which the annual out-of-
10 pocket threshold under section 1860D-
11 2(b)(4)(B) would be met for the year.

12 “(H) Other information (not otherwise
13 prohibited in law from being disclosed) that the
14 Secretary determines would provide bene-
15 ficiaries, clinicians, researchers, and the public
16 with helpful information about drug and bio-
17 logical spending and utilization (including
18 trends of such spending and utilization).

19 “(c) MEDICARE COVERED PART D DRUG DASH-
20 BOARD.—

21 “(1) IN GENERAL.—The dashboard established
22 under subsection (a) for part D of title XVIII shall
23 provide the information described in paragraph (2).

24 “(2) INFORMATION DESCRIBED.—The informa-
25 tion described in this paragraph is the following in-

1 formation with respect to covered part D drugs
2 under such part D:

3 “(A) The information described in sub-
4 paragraphs (A) through (D) of subsection
5 (b)(2).

6 “(B) Information on average annual bene-
7 ficiary out-of-pocket costs below and above the
8 annual out-of-pocket threshold under section
9 1860D–2(b)(4)(B) for the current plan year.
10 Such information shall not include out-of-pocket
11 costs for subsidy eligible individuals under sec-
12 tion 1860D–14.

13 “(C) Information on how to access re-
14 sources as described in sections 1860D–1(c)
15 and 1851(d).

16 “(D) For the most recent calendar year for
17 which data is available—

18 “(i) the 15 covered part D drugs with
19 the highest total spending under such part;
20 and

21 “(ii) any covered part D drug for
22 which the average annual per beneficiary
23 spending exceeds the gross spending for
24 covered part D drugs at which the annual
25 out-of-pocket threshold under section

1 1860D–2(b)(4)(B) would be met for the
2 year.

3 “(E) Other information (not otherwise pro-
4 hibited in law from being disclosed) that the
5 Secretary determines would provide bene-
6 ficiaries, clinicians, researchers, and the public
7 with helpful information about covered part D
8 drug spending and utilization (including trends
9 of such spending and utilization).

10 “(d) MEDICAID COVERED OUTPATIENT DRUG DASH-
11 BOARD.—

12 “(1) IN GENERAL.—The dashboard established
13 under subsection (a) for title XIX shall provide the
14 information described in paragraph (2).

15 “(2) INFORMATION DESCRIBED.—The informa-
16 tion described in this paragraph is the following in-
17 formation with respect to covered outpatient drugs
18 under such title:

19 “(A) The information described in sub-
20 paragraphs (A) through (D) of subsection
21 (b)(2).

22 “(B) For the most recent calendar year for
23 which data is available, the 15 covered out-
24 patient drugs with the highest total spending
25 under such title.

1 “(C) Other information (not otherwise pro-
2 hibited in law from being disclosed) that the
3 Secretary determines would provide bene-
4 ficiaries, clinicians, researchers, and the public
5 with helpful information about covered out-
6 patient drug spending and utilization (including
7 trends of such spending and utilization).

8 “(e) DATA FILES.—The Secretary shall make avail-
9 able the underlying data for each dashboard established
10 under subsection (a) in a machine-readable format.”.

11 **SEC. 223. IMPROVING COORDINATION BETWEEN THE FOOD**
12 **AND DRUG ADMINISTRATION AND THE CEN-**
13 **TERS FOR MEDICARE & MEDICAID SERVICES.**

14 (a) IN GENERAL.—

15 (1) PUBLIC MEETING.—

16 (A) IN GENERAL.—Not later than 12
17 months after the date of the enactment of this
18 Act, the Secretary of Health and Human Serv-
19 ices (referred to in this section as the “Sec-
20 retary”) shall convene a public meeting for the
21 purposes of discussing and providing input on
22 improvements to coordination between the Food
23 and Drug Administration and the Centers for
24 Medicare & Medicaid Services in preparing for
25 the availability of novel medical products de-

1 scribed in subsection (c) on the market in the
2 United States.

3 (B) ATTENDEES.—The public meeting
4 shall include—

5 (i) representatives of relevant Federal
6 agencies, including representatives from
7 each of the medical product centers within
8 the Food and Drug Administration and
9 representatives from the coding, coverage,
10 and payment offices within the Centers for
11 Medicare & Medicaid Services;

12 (ii) stakeholders with expertise in the
13 research and development of novel medical
14 products, including manufacturers of such
15 products;

16 (iii) representatives of commercial
17 health insurance payers;

18 (iv) stakeholders with expertise in the
19 administration and use of novel medical
20 products, including physicians; and

21 (v) stakeholders representing patients
22 and with expertise in the utilization of pa-
23 tient experience data in medical product
24 development.

1 (C) TOPICS.—The public meeting shall in-
2 clude a discussion of—

3 (i) the status of the drug and medical
4 device development pipeline related to the
5 availability of novel medical products;

6 (ii) the anticipated expertise necessary
7 to review the safety and effectiveness of
8 such products at the Food and Drug Ad-
9 ministration and current gaps in such ex-
10 pertise, if any;

11 (iii) the expertise necessary to make
12 coding, coverage, and payment decisions
13 with respect to such products within the
14 Centers for Medicare & Medicaid Services,
15 and current gaps in such expertise, if any;

16 (iv) trends in the differences in the
17 data necessary to determine the safety and
18 effectiveness of a novel medical product
19 and the data necessary to determine
20 whether a novel medical product meets the
21 reasonable and necessary requirements for
22 coverage and payment under title XVIII of
23 the Social Security Act pursuant to section
24 1862(a)(1)(A) of such Act (42 U.S.C.
25 1395y(a)(1)(A));

1 (v) the availability of information for
2 sponsors of such novel medical products to
3 meet each of those requirements; and

4 (vi) the coordination of information
5 related to significant clinical improvement
6 over existing therapies for patients between
7 the Food and Drug Administration and the
8 Centers for Medicare & Medicaid Services
9 with respect to novel medical products.

10 (D) TRADE SECRETS AND CONFIDENTIAL
11 INFORMATION.—No information discussed as a
12 part of the public meeting under this paragraph
13 shall be construed as authorizing the Secretary
14 to disclose any information that is a trade se-
15 cret or confidential information subject to sec-
16 tion 552(b)(4) of title 5, United States Code.

17 (2) IMPROVING TRANSPARENCY OF CRITERIA
18 FOR MEDICARE COVERAGE.—

19 (A) DRAFT GUIDANCE.—Not later than 18
20 months after the public meeting under para-
21 graph (1), the Secretary shall update the final
22 guidance titled “National Coverage Determina-
23 tions with Data Collection as a Condition of
24 Coverage: Coverage with Evidence Develop-
25 ment” to address any opportunities to improve

1 the availability and coordination of information
2 as described in clauses (iv) through (vi) of para-
3 graph (1)(C).

4 (B) FINAL GUIDANCE.—Not later than 12
5 months after issuing draft guidance under sub-
6 paragraph (A), the Secretary shall finalize the
7 updated guidance to address any such opportu-
8 nities.

9 (b) REPORT ON CODING, COVERAGE, AND PAYMENT
10 PROCESSES UNDER MEDICARE FOR NOVEL MEDICAL
11 PRODUCTS.—Not later than 12 months after the date of
12 the enactment of this Act, the Secretary shall publish a
13 report on the Internet website of the Department of
14 Health and Human Services regarding processes under
15 the Medicare program under title XVIII of the Social Se-
16 curity Act (42 U.S.C. 1395 et seq.) with respect to the
17 coding, coverage, and payment of novel medical products
18 described in subsection (c). Such report shall include the
19 following:

20 (1) A description of challenges in the coding,
21 coverage, and payment processes under the Medicare
22 program for novel medical products.

23 (2) Recommendations to—

24 (A) incorporate patient experience data
25 (such as the impact of a disease or condition on

1 the lives of patients and patient treatment pref-
2 erences) into the coverage and payment proc-
3 esses within the Centers for Medicare & Med-
4 icaid Services;

5 (B) decrease the length of time to make
6 national and local coverage determinations
7 under the Medicare program (as those terms
8 are defined in subparagraph (A) and (B), re-
9 spectively, of section 1862(l)(6) of the Social
10 Security Act (42 U.S.C. 1395y(l)(6));

11 (C) streamline the coverage process under
12 the Medicare program and incorporate input
13 from relevant stakeholders into such coverage
14 determinations; and

15 (D) identify potential mechanisms to incor-
16 porate novel payment designs similar to those
17 in development in commercial insurance plans
18 and State plans under title XIX of such Act
19 (42 U.S.C. 1396 et seq.) into the Medicare pro-
20 gram.

21 (c) NOVEL MEDICAL PRODUCTS DESCRIBED.—For
22 purposes of this section, a novel medical product described
23 in this subsection is a medical product, including a drug,
24 biological (including gene and cell therapy), or medical de-
25 vice, that has been designated as a breakthrough therapy

1 under section 506(a) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 356(a)), a breakthrough device
3 under section 515B of such Act (21 U.S.C. 360e–3), or
4 a regenerative advanced therapy under section 506(g) of
5 such Act (21 U.S.C. 356(g)).

6 **SEC. 224. PATIENT CONSULTATION IN MEDICARE NA-**
7 **TIONAL AND LOCAL COVERAGE DETERMINA-**
8 **TIONS IN ORDER TO MITIGATE BARRIERS TO**
9 **INCLUSION OF SUCH PERSPECTIVES.**

10 Section 1862(l) of the Social Security Act (42 U.S.C.
11 1395y(l)) is amended by adding at the end the following
12 new paragraph:

13 “(7) PATIENT CONSULTATION IN NATIONAL
14 AND LOCAL COVERAGE DETERMINATIONS.—The Sec-
15 retary may consult with patients and organizations
16 representing patients in making national and local
17 coverage determinations.”.

18 **SEC. 225. GAO STUDY ON INCREASES TO MEDICARE AND**
19 **MEDICAID SPENDING DUE TO COPAYMENT**
20 **COUPONS AND OTHER PATIENT ASSISTANCE**
21 **PROGRAMS.**

22 (a) STUDY.—The Comptroller General of the United
23 States shall conduct a study on the impact of copayment
24 coupons and other patient assistance programs on pre-
25 scription drug pricing and expenditures within the Medi-

1 care and Medicaid programs. The study shall assess the
2 following:

3 (1) The extent to which copayment coupons and
4 other patient assistance programs contribute to in-
5 flated prescription drug prices under such programs.

6 (2) The impact copayment coupons and other
7 patient assistance programs have in the Medicare
8 Part D program established under part D of title
9 XVIII of the Social Security Act (42 U.S.C. 1395w-
10 101 et seq.) on utilization of higher-cost brand drugs
11 and lower utilization of generic drugs in that pro-
12 gram.

13 (3) The extent to which manufacturers report
14 or obtain tax benefits, including deductions of busi-
15 ness expenses and charitable contributions, for any
16 of the following:

17 (A) Offering copayment coupons or other
18 patient assistance programs.

19 (B) Sponsoring manufacturer patient as-
20 sistance programs.

21 (C) Paying for sponsorships at outreach
22 and advocacy events organized by patient as-
23 sistance programs.

24 (4) The efficacy of oversight conducted to en-
25 sure that independent charity patient assistance pro-

1 grams adhere to guidance from the Office of the In-
2 specter General of the Department of Health and
3 Human Services on avoiding waste, fraud, and
4 abuse.

5 (b) DEFINITIONS.—In this section:

6 (1) INDEPENDENT CHARITY PATIENT ASSIST-
7 ANCE PROGRAM.—The term “independent charity
8 patient assistance program” means any organization
9 described in section 501(c)(3) of the Internal Rev-
10 enue Code of 1986 and exempt from taxation under
11 section 501(a) of such Code and which is not a pri-
12 vate foundation (as defined in section 509(a) of such
13 Code) that offers patient assistance.

14 (2) MANUFACTURER.—The term “manufac-
15 turer” has the meaning given that term in section
16 1927(k)(5) of the Social Security Act (42 U.S.C.
17 1396r–8(k)(5)).

18 (3) MANUFACTURER PATIENT ASSISTANCE PRO-
19 GRAM.—The term “manufacturer patient assistance
20 program” means an organization, including a private
21 foundation (as so defined), that is sponsored by, or
22 receives funding from, a manufacturer and that of-
23 fers patient assistance. Such term does not include
24 an independent charity patient assistance program.

1 a shift on program spending, beneficiary cost-shar-
2 ing liability, and utilization management techniques
3 for such drugs and biologicals; and

4 (2) the feasibility and policy implications of
5 shifting coverage of drugs and biologicals for which
6 payment is currently made under such part B to
7 such part D.

8 (b) REPORT.—

9 (1) IN GENERAL.—Not later than June 30,
10 2024, the Commission shall submit to Congress a re-
11 port containing the results of the study conducted
12 under subsection (a).

13 (2) CONTENTS.—The report under paragraph
14 (1) shall include information, and recommendations
15 as the Commission deems appropriate, regarding—

16 (A) formulary design under such part D;

17 (B) the ability of the benefit structure
18 under such part D to control total spending on
19 drugs and biologicals for which payment is cur-
20 rently made under such part B;

21 (C) changes to the bid process under such
22 part D, if any, that may be necessary to inte-
23 grate coverage of such drugs and biologicals
24 into such part D; and

1 (D) any other changes to the program that
2 Congress should consider in determining wheth-
3 er to shift coverage of such drugs and
4 biologicals from such part B to such part D.

5 **SEC. 227. TAKING STEPS TO FULFILL TREATY OBLIGATIONS**
6 **TO TRIBAL COMMUNITIES.**

7 (a) GAO STUDY.—The Comptroller General shall
8 conduct a study regarding access to, and the cost of, pre-
9 scription drugs among Indians. The study shall include—

10 (1) a review of what Indian health programs
11 pay for prescription drugs on reservations and in
12 urban centers relative to other consumers;

13 (2) recommendations to align the value of pre-
14 scription drug discounts available under the Med-
15 icaid drug rebate program established under section
16 1927 of the Social Security Act (42 U.S.C. 1396r-
17 8) with prescription drug discounts available to
18 Tribal communities through the purchased/referred
19 care program of the Indian Health Service for physi-
20 cian administered drugs; and

21 (3) an examination of how Tribal communities
22 and urban Indian organizations utilize the Medicare
23 part D program established under title XVIII of the
24 Social Security Act (42 U.S.C. 1395w-101 et seq.)

1 and recommendations to improve enrollment among
2 Indians in that program.

3 (b) REPORT.—Not later than 18 months after the
4 date of the enactment of this Act, the Comptroller General
5 shall submit to Congress a report containing the results
6 of the study conducted under subsection (a), together with
7 recommendations for such legislation and administrative
8 action as the Comptroller General determines appropriate.

9 (c) DEFINITIONS.—In this section:

10 (1) COMPTROLLER GENERAL.—The term
11 “Comptroller General” means the Comptroller Gen-
12 eral of the United States.

13 (2) INDIAN; INDIAN HEALTH PROGRAM; INDIAN
14 TRIBE.—The terms “Indian”, “Indian health pro-
15 gram”, and “Indian tribe” have the meanings given
16 those terms in section 4 of the Indian Health Care
17 Improvement Act (25 U.S.C. 1603).

18 **TITLE III—MEDICAID**

19 **SEC. 301. MEDICAID PHARMACY AND THERAPEUTICS COM- 20 MITTEE IMPROVEMENTS.**

21 (a) IN GENERAL.—Subparagraph (A) of section
22 1927(d)(4) of the Social Security Act (42 U.S.C. 1396r-
23 8(d)(4)) is amended to read as follows:

24 “(A)(i) The formulary is developed and re-
25 viewed by a pharmacy and therapeutics com-

1 mittee consisting of physicians, pharmacists,
2 and other appropriate individuals appointed by
3 the Governor of the State.

4 “(ii) Subject to clause (vi), the State estab-
5 lishes and implements a conflict of interest pol-
6 icy for the pharmacy and therapeutics com-
7 mittee that—

8 “(I) is publicly accessible;

9 “(II) requires all committee members
10 to complete, on at least an annual basis, a
11 disclosure of relationships, associations,
12 and financial dealings that may affect their
13 independence of judgement in committee
14 matters; and

15 “(III) contains clear processes, such
16 as recusal from voting or discussion, for
17 those members who report a conflict of in-
18 terest, along with appropriate processes to
19 address any instance where a member fails
20 to report a conflict of interest.

21 “(iii) The membership of the pharmacy
22 and therapeutics committee—

23 “(I) includes at least 1 actively prac-
24 ticing physician and at least 1 actively
25 practicing pharmacist, each of whom—

1 “(aa) is independent and free of
2 conflict with respect to manufacturers
3 and Medicaid participating plans or
4 subcontractors, including pharmacy
5 benefit managers; and

6 “(bb) has expertise in the care of
7 1 or more Medicaid-specific popu-
8 lations such as elderly or disabled in-
9 dividuals, children with complex med-
10 ical needs, or low-income individuals
11 with chronic illnesses and

12 “(II) is made publicly available.

13 “(iv) At the option of the State, the
14 State’s drug use review board established under
15 subsection (g)(3) may serve as the pharmacy
16 and therapeutics committee provided the State
17 ensures that such board meets the requirements
18 of clauses (ii) and (iii).

19 “(v) The State reviews and has final ap-
20 proval of the formulary established by the phar-
21 macy and therapeutics committee.

22 “(vi) If the Secretary determines it appro-
23 priate or necessary based on the findings and
24 recommendations of the Comptroller General of
25 the United States in the report submitted to

1 Congress under section 203 of the Prescription
2 Drug Pricing Reduction Act of 2021, the Sec-
3 retary shall issue guidance that States must fol-
4 low for establishing conflict of interest policies
5 for the pharmacy and therapeutics committee in
6 accordance with the requirements of clause (ii),
7 including appropriate standards and require-
8 ments for identifying, addressing, and reporting
9 on conflicts of interest.”.

10 (b) APPLICATION TO MEDICAID MANAGED CARE OR-
11 GANIZATIONS.—Clause (xiii) of section 1903(m)(2)(A) of
12 the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is
13 amended—

14 (1) by striking “and (III)” and inserting
15 “(III)”;

16 (2) by striking the period at the end and insert-
17 ing “, and (IV) any formulary used by the entity for
18 covered outpatient drugs dispensed to individuals eli-
19 gible for medical assistance who are enrolled with
20 the entity is developed and reviewed by a pharmacy
21 and therapeutics committee that meets the require-
22 ments of clauses (ii) and (iii) of section
23 1927(d)(4)(A).”; and

24 (3) by moving the left margin 2 ems to the left.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall take effect on the date that is 1 year
3 after the date of enactment of this Act.

4 **SEC. 302. IMPROVING REPORTING REQUIREMENTS AND DE-**
5 **VELOPING STANDARDS FOR THE USE OF**
6 **DRUG USE REVIEW BOARDS IN STATE MED-**
7 **ICAID PROGRAMS.**

8 (a) IN GENERAL.—Section 1927(g)(3) of the Social
9 Security Act (42 U.S.C. 1396r–8(g)(3)) is amended—
10 (1) by amending subparagraph (B) to read as
11 follows:

12 “(B) MEMBERSHIP.—

13 “(i) IN GENERAL.—The membership
14 of the DUR Board shall include health
15 care professionals who have recognized
16 knowledge and expertise in one or more of
17 the following:

18 “(I) The clinically appropriate
19 prescribing of covered outpatient
20 drugs.

21 “(II) The clinically appropriate
22 dispensing and monitoring of covered
23 outpatient drugs.

24 “(III) Drug use review, evalua-
25 tion, and intervention.

1 “(IV) Medical quality assurance.

2 “(ii) MEMBERSHIP REQUIREMENTS.—

3 The membership of the DUR Board
4 shall—

5 “(I) be made up of at least $\frac{1}{3}$
6 but no more than 51 percent members
7 who are licensed and actively prac-
8 ticing physicians and at least $\frac{1}{3}$ mem-
9 bers who are licensed and actively
10 practicing pharmacists; and

11 “(II) include at least 1 licensed
12 and actively practicing physician and
13 at least 1 licensed and actively prac-
14 ticing pharmacist, each of whom—

15 “(aa) is independent and
16 free of any conflict, including
17 with respect to manufacturers,
18 medicaid managed care entities,
19 or pharmacy benefit managers;
20 and

21 “(bb) has expertise in the
22 care of 1 or more categories of
23 individuals who are likely to be
24 eligible for benefits under this
25 title, including elderly or disabled

1 individuals, children with complex
2 medical needs, or low-income in-
3 dividuals with chronic illnesses;
4 and

5 “(III) be made publicly available.

6 “(iii) CONFLICT OF INTEREST POL-
7 ICY.—The State shall establish and imple-
8 ment a conflict of interest policy for the
9 DUR Board that—

10 “(I) is publicly accessible;

11 “(II) requires all board members
12 to complete, on at least an annual
13 basis, a disclosure of relationships, as-
14 sociations, and financial dealings that
15 may affect their independence of
16 judgement in board matters; and

17 “(III) contains clear processes,
18 such as recusal from voting or discus-
19 sion, for those members who report a
20 conflict of interest, along with appro-
21 priate processes to address any in-
22 stance where a member fails to report
23 a conflict of interest.”; and

24 (2) by adding at the end the following new sub-
25 paragraph:

1 “(E) DUR BOARD MEMBERSHIP RE-
2 PORTS.—

3 “(i) DUR BOARD REPORTS.—Each
4 State shall require the DUR Board to pre-
5 pare and submit to the State an annual re-
6 port on the DUR Board membership. Each
7 such report shall include any conflicts of
8 interest with respect to members of the
9 DUR Board that the DUR Board recorded
10 or was aware of during the period that is
11 the subject of the report, and the process
12 applied to address such conflicts of inter-
13 est, in addition to any other information
14 required by the State.

15 “(ii) INCLUSION OF DUR BOARD MEM-
16 BERSHIP INFORMATION IN STATE RE-
17 PORTS.—Each annual State report to the
18 Secretary required under subparagraph
19 (D) shall include—

20 “(I) the number of individuals
21 serving on the State’s DUR Board;

22 “(II) the names and professions
23 of the individuals serving on such
24 DUR Board;

1 “(III) any conflicts of interest or
2 recusals with respect to members of
3 such DUR Board reported by the
4 DUR Board or that the State was
5 aware of during the period that is the
6 subject of the report; and

7 “(IV) whether the State has
8 elected for such DUR Board to serve
9 as the committee responsible for de-
10 veloping a State formulary under sub-
11 section (d)(4)(A).”.

12 (b) **MANAGED CARE REQUIREMENTS.**—Section
13 1932(i) of the Social Security Act (42 U.S.C. 1396u–2(i))
14 is amended—

15 (1) by striking “section 483.3(s)(4)” and in-
16 serting “section 438.3(s)(4)”;

17 (2) by striking “483.3(s)(5)” and inserting
18 “438.3(s)(5)”;

19 (3) by adding at the end the following: “Such
20 a managed care entity shall not be considered to be
21 in compliance with the requirement of such section
22 438.3(s)(5) that the entity provide a detailed de-
23 scription of its drug utilization review activities un-
24 less the entity includes a description of the prospec-
25 tive drug review activities described in paragraph

1 (2)(A) of section 1927(g) and the activities listed in
2 paragraph (3)(C) of section 1927(g), makes the un-
3 derlying drug utilization review data available to the
4 State and the Secretary, and provides such other in-
5 formation as deemed appropriate by the Secretary.”.

6 (c) DEVELOPMENT OF NATIONAL STANDARDS FOR
7 MEDICAID DRUG USE REVIEW.—The Secretary of Health
8 and Human Services may promulgate regulations or guid-
9 ance establishing national standards for Medicaid drug
10 use review programs under section 1927(g) of the Social
11 Security Act (42 U.S.C. 1396r–8) and drug utilization re-
12 view activities and requirements under section 1932(i) of
13 such Act (42 U.S.C. 1396u–2(i)), for the purpose of align-
14 ing review criteria for prospective and retrospective drug
15 use review across all State Medicaid programs.

16 (d) CMS GUIDANCE.—Not later than 18 months
17 after the date of enactment of this Act, the Secretary of
18 Health and Human Services shall issue guidance—

19 (1) outlining steps that States must take to
20 come into compliance with statutory and regulatory
21 requirements for prospective and retrospective drug
22 use review under section 1927(g) of the Social Secu-
23 rity Act (42 U.S.C. 1396r–8(g)) and drug utilization
24 review activities and requirements under section
25 1932(i) of such Act (42 U.S.C. 1396u–2(i)) (includ-

1 ing with respect to requirements that were in effect
2 before the date of enactment of this Act); and

3 (2) describing the actions that the Secretary
4 will take to enforce such requirements.

5 (e) EFFECTIVE DATE.—The amendments made by
6 this section shall take effect on the date that is 1 year
7 after the date of enactment of this Act.

8 **SEC. 303. GAO REPORT ON CONFLICTS OF INTEREST IN**
9 **STATE MEDICAID PROGRAM DRUG USE RE-**
10 **VIEW BOARDS AND PHARMACY AND THERA-**
11 **PEUTICS (P&T) COMMITTEES.**

12 (a) INVESTIGATION.—The Comptroller General of the
13 United States shall conduct an investigation of potential
14 or existing conflicts of interest among members of State
15 Medicaid program State drug use review boards (in this
16 section referred to as “DUR Boards”) and pharmacy and
17 therapeutics committees (in this section referred to as
18 “P&T Committees”).

19 (b) REPORT.—Not later than 24 months after the
20 date of enactment of this Act, the Comptroller General
21 shall submit to Congress a report on the investigation con-
22 ducted under subsection (a) that includes the following:

23 (1) A description outlining how DUR Boards
24 and P&T Committees operate in States, including
25 details with respect to—

1 (A) the structure and operation of DUR
2 Boards and statewide P&T Committees;

3 (B) States that operate separate P&T
4 Committees for their fee-for-service Medicaid
5 program and their Medicaid managed care or-
6 ganizations or other Medicaid managed care ar-
7 rangements (collectively referred to in this sec-
8 tion as “Medicaid MCOs”); and

9 (C) States that allow Medicaid MCOs to
10 have their own P&T Committees and the extent
11 to which pharmacy benefit managers administer
12 or participate in such P&T Committees.

13 (2) A description outlining the differences be-
14 tween DUR Boards established in accordance with
15 section 1927(g)(3) of the Social Security Act (42
16 U.S.C. 1396r(g)(3)) and P&T Committees.

17 (3) A description outlining the tools P&T Com-
18 mittees may use to determine Medicaid drug cov-
19 erage and utilization management policies.

20 (4) An analysis of whether and how States or
21 P&T Committees establish participation and inde-
22 pendence requirements for DUR Boards and P&T
23 Committees, including with respect to entities with
24 connections with drug manufacturers, State Med-
25 icaid programs, managed care organizations, and

1 other entities or individuals in the pharmaceutical
2 industry.

3 (5) A description outlining how States, DUR
4 Boards, or P&T Committees define conflicts of inter-
5 est.

6 (6) A description of how DUR Boards and P&T
7 Committees address conflicts of interest, including
8 who is responsible for implementing such policies.

9 (7) A description of the tools, if any, States use
10 to ensure that there are no conflicts of interest on
11 DUR Boards and P&T Committees.

12 (8) An analysis of the effectiveness of tools
13 States use to ensure that there are no conflicts of
14 interest on DUR Boards and P&T Committees and,
15 if applicable, recommendations as to how such tools
16 could be improved.

17 (9) A review of strategies States may use to
18 guard against conflicts of interest on DUR Boards
19 and P&T Committees and to ensure compliance with
20 the requirements of titles XI and XIX of the Social
21 Security Act (42 U.S.C. 1301 et seq., 1396 et seq.)
22 and access to effective, clinically appropriate, and
23 medically necessary drug treatments for Medicaid
24 beneficiaries, including recommendations for such

1 legislative and administrative actions as the Comp-
2 troller General determines appropriate.

3 **SEC. 304. ENSURING THE ACCURACY OF MANUFACTURER**
4 **PRICE AND DRUG PRODUCT INFORMATION**
5 **UNDER THE MEDICAID DRUG REBATE PRO-**
6 **GRAM.**

7 (a) AUDIT OF MANUFACTURER PRICE AND DRUG
8 PRODUCT INFORMATION.—

9 (1) IN GENERAL.—Subparagraph (B) of section
10 1927(b)(3) of the Social Security Act (42 U.S.C.
11 1396r–8(b)(3)) is amended to read as follows:

12 “(B) AUDITS AND SURVEYS OF MANUFAC-
13 Turer PRICE AND DRUG PRODUCT INFORMA-
14 TION.—

15 “(i) AUDITS.—The Secretary shall
16 conduct ongoing audits of the price and
17 drug product information reported by man-
18 ufacturers under subparagraph (A) for the
19 most recently ended rebate period to en-
20 sure the accuracy and timeliness of such
21 information. In conducting such audits, the
22 Secretary may employ evaluations, surveys,
23 statistical sampling, predictive analytics
24 and other relevant tools and methods .

1 “(ii) VERIFICATIONS SURVEYS OF AV-
2 ERAGE MANUFACTURER PRICE AND MANU-
3 FACTURER’S AVERAGE SALES PRICE.—In
4 addition to the audits required under
5 clause (i), the Secretary may survey whole-
6 salers and manufacturers (including manu-
7 facturers that directly distribute their cov-
8 ered outpatient drugs (in this subpara-
9 graph referred to as ‘direct sellers’)), when
10 necessary, to verify manufacturer prices
11 and manufacturer’s average sales prices
12 (including wholesale acquisition cost) to
13 make payment reported under subpara-
14 graph (A).

15 “(iii) PENALTIES.—In addition to
16 other penalties as may be prescribed by
17 law, including under subparagraph (C) of
18 this paragraph, the Secretary may impose
19 a civil monetary penalty in an amount not
20 to exceed \$185,000 on an annual basis on
21 a wholesaler, manufacturer, or direct sell-
22 er, if the wholesaler, manufacturer, or di-
23 rect seller of a covered outpatient drug re-
24 fuses a request for information about
25 charges or prices by the Secretary in con-

1 nection with an audit or survey under this
2 subparagraph or knowingly provides false
3 information. The provisions of section
4 1128A (other than subsections (a) (with
5 respect to amounts of penalties or addi-
6 tional assessments) and (b)) shall apply to
7 a civil money penalty under this clause in
8 the same manner as such provisions apply
9 to a penalty or proceeding under section
10 1128A(a).

11 “(iv) REPORTS.—

12 “(I) REPORT TO CONGRESS.—

13 The Secretary shall, not later than 18
14 months after date of enactment of
15 this subparagraph, submit a report to
16 the Committee on Energy and Com-
17 merce of the House of Representatives
18 and the Committee on Finance of the
19 Senate regarding additional regulatory
20 or statutory changes that may be re-
21 quired in order to ensure accurate and
22 timely reporting and oversight of
23 manufacturer price and drug product
24 information, including whether
25 changes should be made to reasonable

1 assumption requirements to ensure
2 such assumptions are reasonable and
3 accurate or whether another method-
4 ology for ensuring accurate and timely
5 reporting of price and drug product
6 information should be considered to
7 ensure the integrity of the drug rebate
8 program under this section.

9 “(II) ANNUAL REPORTS.—The
10 Secretary shall, on at least an annual
11 basis, submit a report to the Com-
12 mittee on Energy and Commerce of
13 the House of Representatives and the
14 Committee on Finance of the Senate
15 summarizing the results of the audits
16 and surveys conducted under this sub-
17 paragraph during the period that is
18 the subject of the report.

19 “(III) CONTENT.—Each report
20 submitted under subclause (II) shall,
21 with respect to the period that is the
22 subject of the report, include sum-
23 maries of—

24 “(aa) error rates in the
25 price, drug product, and other

1 relevant information supplied by
2 manufacturers under subpara-
3 graph (A);
4 “(bb) the timeliness with
5 which manufacturers, whole-
6 salers, and direct sellers provide
7 information required under sub-
8 paragraph (A) or under clause (i)
9 or (ii) of this subparagraph;
10 “(cc) the number of manu-
11 facturers, wholesalers, and direct
12 sellers and drug products audited
13 under this subparagraph;
14 “(dd) the types of price and
15 drug product information re-
16 viewed under the audits con-
17 ducted under this subparagraph;
18 “(ee) the tools and meth-
19 odologies employed in such au-
20 dits;
21 “(ff) the findings of such
22 audits, including which manufac-
23 turers, if any, were penalized
24 under this subparagraph; and

1 “(gg) such other relevant in-
2 formation as the Secretary shall
3 deem appropriate.

4 “(IV) PROTECTION OF INFORMA-
5 TION.—In preparing a report required
6 under subclause (II), the Secretary
7 shall redact such proprietary informa-
8 tion as the Secretary determines ap-
9 propriate to prevent disclosure of, and
10 to safeguard, such information.

11 “(v) APPROPRIATIONS.—Out of any
12 funds in the Treasury not otherwise appro-
13 priated, there is appropriated to the Sec-
14 retary \$2,000,000 for fiscal year 2023 and
15 each fiscal year thereafter to carry out this
16 subparagraph.”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by this subsection shall take effect on the first day
19 of the first fiscal quarter that begins after the date
20 of enactment of this Act.

21 (b) INCREASED PENALTIES FOR NONCOMPLIANCE
22 WITH REPORTING REQUIREMENTS.—

23 (1) INCREASED PENALTY FOR LATE REPORTING
24 OF INFORMATION.—Section 1927(b)(3)(C)(i) of the
25 Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(i))

1 is amended by striking “increased by \$10,000 for
2 each day in which such information has not been
3 provided and such amount shall be paid to the
4 Treasury” and inserting “, for each covered out-
5 patient drug with respect to which such information
6 is not provided, \$50,000 for the first day that such
7 information is not provided on a timely basis and
8 \$19,000 for each subsequent day that such informa-
9 tion is not provided”.

10 (2) INCREASED PENALTY FOR KNOWINGLY RE-
11 PORTING FALSE INFORMATION.—Section
12 1927(b)(3)(C)(ii) of the Social Security Act (42
13 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking
14 “\$100,000” and inserting “\$500,000”.

15 (3) EFFECTIVE DATE.—The amendments made
16 by this subsection shall take effect on the first day
17 of the first fiscal quarter that begins after the date
18 of enactment of this Act.

19 **SEC. 305. T-MSIS DRUG DATA ANALYTICS REPORTS.**

20 (a) IN GENERAL.—Not later than May 1 of each cal-
21 endar year beginning with calendar year 2024, the Sec-
22 retary of Health and Human Services (in this section re-
23 ferred to as the “Secretary”) shall publish on a website
24 of the Centers for Medicare & Medicaid Services that is
25 accessible to the public a report of the most recently avail-

1 able data on provider prescribing patterns under the Med-
2 icaid program.

3 (b) CONTENT OF REPORT.—

4 (1) REQUIRED CONTENT.—Each report re-
5 quired under subsection (a) for a calendar year shall
6 include the following information with respect to
7 each State (and, to the extent available, with respect
8 to Puerto Rico, the United States Virgin Islands,
9 Guam, the Northern Mariana Islands, and American
10 Samoa):

11 (A) A comparison of covered outpatient
12 drug (as defined in section 1927(k)(2) of the
13 Social Security Act (42 U.S.C. 1396r–8(k)(2)))
14 prescribing patterns under the State Medicaid
15 plan or waiver of such plan (including drugs
16 prescribed on a fee-for-service basis and drugs
17 prescribed under managed care arrangements
18 under such plan or waiver)—

19 (i) across all forms or models of reim-
20 bursement used under the plan or waiver;

21 (ii) within specialties and subspecial-
22 ties, as defined by the Secretary;

23 (iii) by episodes of care for—

24 (I) each chronic disease category,
25 as defined by the Secretary, that is

1 represented in the 10 conditions that
2 accounted for the greatest share of
3 total spending under the plan or waiv-
4 er during the year that is the subject
5 of the report;

6 (II) procedural groupings; and

7 (III) rare disease diagnosis codes;

8 (iv) by patient demographic character-
9 istics, including race (to the extent that
10 the Secretary determines that there is suf-
11 ficient data available with respect to such
12 characteristic in a majority of States), gen-
13 der, and age;

14 (v) by patient high-utilizer or risk sta-
15 tus; and

16 (vi) by high and low resource settings
17 by facility and place of service categories,
18 as determined by the Secretary.

19 (B) In the case of medical assistance for
20 covered outpatient drugs (as so defined) pro-
21 vided under a State Medicaid plan or waiver of
22 such plan in a managed care setting, an anal-
23 ysis of the differences in managed care pre-
24 scribing patterns when a covered outpatient
25 drug is prescribed in a managed care setting as

1 compared to when the drug is prescribed in a
2 fee-for-service setting.

3 (2) ADDITIONAL CONTENT.—A report required
4 under subsection (a) for a calendar year may include
5 State-specific information about prescription utiliza-
6 tion management tools under State Medicaid plans
7 or waivers of such plans, including—

8 (A) a description of prescription utilization
9 management tools under State programs to pro-
10 vide long-term services and supports under a
11 State Medicaid plan or a waiver of such plan;

12 (B) a comparison of prescription utilization
13 management tools applicable to populations cov-
14 ered under a State Medicaid plan waiver under
15 section 1115 of the Social Security Act (42
16 U.S.C. 1315) and the models applicable to pop-
17 ulations that are not covered under the waiver;

18 (C) a comparison of the prescription utili-
19 zation management tools employed by different
20 Medicaid managed care organizations, phar-
21 macy benefit managers, and related entities
22 within the State;

23 (D) a comparison of the prescription utili-
24 zation management tools applicable to each en-

1 rollment category under a State Medicaid plan
2 or waiver; and

3 (E) a comparison of the prescription utili-
4 zation management tools applicable under the
5 State Medicaid plan or waiver by patient high-
6 utilizer or risk status.

7 (3) ADDITIONAL ANALYSIS.—To the extent
8 practicable, the Secretary shall include in each re-
9 port published under subsection (a)—

10 (A) analyses of national, State, and local
11 patterns of Medicaid population-based pre-
12 scribing behaviors; and

13 (B) recommendations for administrative or
14 legislative action to improve the effectiveness of,
15 and reduce costs for, covered outpatient drugs
16 under Medicaid while ensuring timely bene-
17 ficiary access to medically necessary covered
18 outpatient drugs.

19 (c) USE OF T-MSIS DATA.—Each report required
20 under subsection (a) shall—

21 (1) be prepared using data and definitions from
22 the Transformed Medicaid Statistical Information
23 System (“T-MSIS”) data set (or a successor data
24 set) that is not more than 24 months old on the date
25 that the report is published; and

1 ered outpatient drugs that are potentially curative
2 treatments intended for one-time use that are ad-
3 ministered to individuals under this title by entering
4 into a risk-sharing value-based payment agreement
5 with the manufacturer of the drug in accordance
6 with the requirements of this subsection.

7 “(2) SECRETARIAL APPROVAL.—

8 “(A) IN GENERAL.—A State shall submit a
9 request to the Secretary to enter into a risk-
10 sharing value based payment agreement, and
11 the Secretary shall not approve a proposed risk-
12 sharing value-based payment agreement be-
13 tween a State and a manufacturer for payment
14 for a covered outpatient drug of the manufac-
15 turer unless the following requirements are met:

16 “(i) MANUFACTURER IS PARTY TO RE-
17 BATE AGREEMENT AND IN COMPLIANCE
18 WITH REQUIREMENTS.—The manufacturer
19 has a rebate agreement in effect as re-
20 quired under subsection (a) and (b) of this
21 section and is in compliance with all appli-
22 cable requirements under this title.

23 “(ii) NO INCREASE TO PROJECTED
24 NET FEDERAL SPENDING.—

1 “(I) IN GENERAL.—The Chief
2 Actuary certifies that the projected
3 payments for each covered outpatient
4 drug under such proposed agreement
5 would not result in greater estimated
6 Federal spending under this title than
7 the net Federal spending that would
8 result in the absence of the agree-
9 ment.

10 “(II) NET FEDERAL SPENDING
11 DEFINED.—For purposes of this sub-
12 section, the term ‘net Federal spend-
13 ing’ means the amount of Federal
14 payments the Chief Actuary estimates
15 would be made under this title for ad-
16 ministering a covered outpatient drug
17 to an individual eligible for medical
18 assistance under a State plan or a
19 waiver of such plan, reduced by the
20 amount of all rebates the Chief Actu-
21 ary estimates would be paid with re-
22 spect to the administering of such
23 drug, including all rebates under this
24 title and any supplemental or other

1 additional rebates, in the absence of
2 such an agreement.

3 “(III) INFORMATION.—The Chief
4 Actuary shall make the certifications
5 required under this clause based on
6 the most recently available and reli-
7 able drug pricing and product infor-
8 mation. The State and manufacturer
9 shall provide the Secretary and the
10 Chief Actuary with all necessary infor-
11 mation required to make the estimates
12 needed for such certifications.

13 “(iii) LAUNCH AND LIST PRICE JUS-
14 TIFICATIONS.—The manufacturer submits
15 all relevant information and supporting
16 documentation necessary for pricing deci-
17 sions as deemed appropriate by the Sec-
18 retary, which shall be truthful and non-
19 misleading, including manufacturer infor-
20 mation and supporting documentation for
21 launch price or list price increases, and
22 any applicable justification required under
23 section 1128L.

24 “(iv) CONFIDENTIALITY OF INFORMA-
25 TION; PENALTIES.—The provisions of sub-

1 paragraphs (C) and (D) of subsection
2 (b)(3) shall apply to a manufacturer that
3 fails to submit the information and docu-
4 mentation required under clauses (ii) and
5 (iii) on a timely basis, or that knowingly
6 provides false or misleading information, in
7 the same manner as such provisions apply
8 to a manufacturer with a rebate agreement
9 under this section.

10 “(B) CONSIDERATION OF STATE REQUEST
11 FOR APPROVAL.—

12 “(i) IN GENERAL.—The Secretary
13 shall treat a State request for approval of
14 a risk-sharing value-based payment agree-
15 ment in the same manner that the Sec-
16 retary treats a State plan amendment, and
17 subpart B of part 430 of title 42, Code of
18 Federal Regulations, including, subject to
19 clause (ii), the timing requirements of sec-
20 tion 430.16 of such title (as in effect on
21 the date of enactment of this subsection),
22 shall apply to a request for approval of a
23 risk-sharing value-based payment agree-
24 ment in the same manner as such subpart
25 applies to a State plan amendment.

1 “(ii) TIMING.—The Secretary shall
2 consult with the Commissioner of Food
3 and Drugs as required under subpara-
4 graph (C) and make a determination on
5 whether to approve a request from a State
6 for approval of a proposed risk-sharing
7 value-based payment agreement (or request
8 additional information necessary to allow
9 the Secretary to make a determination
10 with respect to such request for approval)
11 within the time period, to the extent prac-
12 ticable, specified in section 430.16 of title
13 42, Code of Federal Regulations (as in ef-
14 fect on the date of enactment of this sub-
15 section), but in no case shall the Secretary
16 take more than 180 days after the receipt
17 of such request for approval or response to
18 such request for additional information to
19 make such a determination (or request ad-
20 ditional information).

21 “(C) CONSULTATION WITH THE COMMIS-
22 SIONER OF FOOD AND DRUGS.—In considering
23 whether to approve a risk-sharing value-based
24 payment agreement, the Secretary, to the ex-
25 tent necessary, shall consult with the Commis-

1 sioner of Food and Drugs to determine whether
2 the relevant clinical parameters specified in
3 such agreement are appropriate.

4 “(3) INSTALLMENT-BASED PAYMENT STRUC-
5 TURE.—

6 “(A) IN GENERAL.—A risk-sharing value-
7 based payment agreement shall provide for a
8 payment structure under which, for every in-
9 stallment year of the agreement (subject to sub-
10 paragraph (B)), the State shall pay the total in-
11 stallment year amount in equal installments to
12 be paid at regular intervals over a period of
13 time that shall be specified in the agreement.

14 “(B) REQUIREMENTS FOR INSTALLMENT
15 PAYMENTS.—

16 “(i) TIMING OF FIRST PAYMENT.—
17 The State shall make the first of the in-
18 stallment payments described in subpara-
19 graph (A) for an installment year not later
20 than 30 days after the end of such year.

21 “(ii) LENGTH OF INSTALLMENT PE-
22 RIOD.—The period of time over which the
23 State shall make the installment payments
24 described in subparagraph (A) for an in-

1 stallment year shall not be longer than 5
2 years.

3 “(iii) NONPAYMENT OR REDUCED
4 PAYMENT OF INSTALLMENTS FOLLOWING
5 A FAILURE TO MEET CLINICAL PARAM-
6 ETER.—If, prior to the payment date (as
7 specified in the agreement) of any install-
8 ment payment described in subparagraph
9 (A) or any other alternative date or time
10 frame (as otherwise specified in the agree-
11 ment), the covered outpatient drug which
12 is subject to the agreement fails to meet a
13 relevant clinical parameter of the agree-
14 ment, the agreement shall provide that—

15 “(I) the installment payment
16 shall not be made; or

17 “(II) the installment payment
18 shall be reduced by a percentage spec-
19 ified in the agreement that is based
20 on the outcome achieved by the drug
21 relative to the relevant clinical param-
22 eter.

23 “(4) NOTICE OF INTENT.—

24 “(A) IN GENERAL.—Subject to subpara-
25 graph (B), a manufacturer of a covered out-

1 patient drug shall not be eligible to enter into
2 a risk-sharing value-based payment agreement
3 under this subsection with respect to such drug
4 unless the manufacturer notifies the Secretary
5 that the manufacturer is interested in entering
6 into such an agreement with respect to such
7 drug. The decision to submit and timing of a
8 request to enter into a proposed risk-sharing
9 value-based payment agreement shall remain
10 solely within the discretion of the State and
11 shall only be effective upon Secretarial approval
12 as required under this subsection.

13 “(B) TREATMENT OF SUBSEQUENTLY AP-
14 PROVED DRUGS.—

15 “(i) IN GENERAL.—In the case of a
16 manufacturer of a covered outpatient drug
17 approved under section 505 of the Federal
18 Food, Drug, and Cosmetic Act or licensed
19 under section 351 of the Public Health
20 Service Act after the date of enactment of
21 this subsection, not more than 90 days
22 after meeting with the Food and Drug Ad-
23 ministration following phase II clinical
24 trials for such drug (or, in the case of a
25 drug described in clause (ii), not later than

1 March 31, 2025), the manufacturer must
2 notify the Secretary of the manufacturer's
3 intent to enter into a risk-sharing value-
4 based payment agreement under this sub-
5 section with respect to such drug. If no
6 such meeting has occurred, the Secretary
7 may use discretion as to whether a poten-
8 tially curative treatment intended for one-
9 time use may qualify for a risk-sharing
10 value-based payment agreement under this
11 section. A manufacturer notification of in-
12 terest shall not have any influence on a de-
13 cision for approval by the Food and Drug
14 Administration.

15 “(ii) APPLICATION TO CERTAIN SUB-
16 SEQUENTLY APPROVED DRUGS.—A drug
17 described in this clause is a covered out-
18 patient drug of a manufacturer—

19 “(I) that is approved under sec-
20 tion 505 of the Federal Food, Drug,
21 and Cosmetic Act or licensed under
22 section 351 of the Public Health Serv-
23 ice Act after the date of enactment of
24 this subsection; and

1 “(II) with respect to which, as of
2 January 1, 2025, more than 90 days
3 have passed after the manufacturer’s
4 meeting with the Food and Drug Ad-
5 ministration following phase II clinical
6 trials for such drug.

7 “(iii) PARALLEL APPROVAL.—The
8 Secretary, in coordination with the Admin-
9 istrator of the Centers for Medicare &
10 Medicaid Services and the Commissioner of
11 Food and Drugs, shall, to the extent prac-
12 ticable, approve a State’s request to enter
13 into a proposed risk-sharing value-based
14 payment agreement that otherwise meets
15 the requirements of this subsection at the
16 time that such a drug is approved by the
17 Food and Drug Administration to help
18 provide that no State that wishes to enter
19 into such an agreement is required to pay
20 for the drug in full at one time if the State
21 is seeking to pay over a period of time as
22 outlined in the proposed agreement.

23 “(iv) RULE OF CONSTRUCTION.—
24 Nothing in this paragraph shall be applied
25 or construed to modify or affect the time-

1 frames or factors involved in the Sec-
2 retary's determination of whether to ap-
3 prove or license a drug under section 505
4 of the Federal Food, Drug, and Cosmetic
5 Act or section 351 of the Public Health
6 Service Act.

7 “(5) SPECIAL PAYMENT RULES.—

8 “(A) IN GENERAL.—Except as otherwise
9 provided in this paragraph, with respect to an
10 individual who is administered a unit of a cov-
11 ered outpatient drug that is purchased under a
12 State plan by a State Medicaid agency under a
13 risk-sharing value-based payment agreement in
14 an installment year, the State shall remain lia-
15 ble to the manufacturer of such drug for pay-
16 ment for such unit without regard to whether
17 the individual remains enrolled in the State
18 plan under this title (or a waiver of such plan)
19 for each installment year for which the State is
20 to make installment payments for covered out-
21 patient drugs purchased under the agreement
22 in such year.

23 “(B) DEATH.—In the case of an individual
24 described in subparagraph (A) who dies during
25 the period described in such subparagraph, the

1 State plan shall not be liable for any remaining
2 payment for the unit of the covered outpatient
3 drug administered to the individual which is
4 owed under the agreement described in such
5 subparagraph.

6 “(C) WITHDRAWAL OF APPROVAL.—In the
7 case of a covered outpatient drug that is the
8 subject of a risk-sharing value-based agreement
9 between a State and a manufacturer under this
10 subsection, including a drug approved in ac-
11 cordance with section 506(c) of the Federal
12 Food, Drug, and Cosmetic Act, and such drug
13 is the subject of an application that has been
14 withdrawn by the Secretary, the State plan
15 shall not be liable for any remaining payment
16 that is owed under the agreement.

17 “(D) ALTERNATIVE ARRANGEMENT UNDER
18 AGREEMENT.—Subject to approval by the Sec-
19 retary, the terms of a proposed risk-sharing
20 value-based payment agreement submitted for
21 approval by a State may provide that subpara-
22 graph (A) shall not apply.

23 “(E) GUIDANCE.—Not later than January
24 1, 2025, the Secretary shall issue guidance to
25 States establishing a process for States to no-

1 tify the Secretary when an individual who is ad-
2 ministered a unit of a covered outpatient drug
3 that is purchased by a State plan under a risk-
4 sharing value-based payment agreement ceases
5 to be enrolled under the State plan under this
6 title (or a waiver of such plan) or dies before
7 the end of the installment period applicable to
8 such unit under the agreement.

9 “(6) TREATMENT OF PAYMENTS UNDER RISK-
10 SHARING VALUE-BASED AGREEMENTS FOR PUR-
11 POSES OF AVERAGE MANUFACTURER PRICE; BEST
12 PRICE.—The Secretary shall treat any payments
13 made to the manufacturer of a covered outpatient
14 drug under a risk-sharing value-based payment
15 agreement under this subsection during a rebate pe-
16 riod in the same manner that the Secretary treats
17 payments made under a State supplemental rebate
18 agreement under sections 447.504(c)(19) and
19 447.505(c)(7) of title 42, Code of Federal Regula-
20 tions (or any successor regulations) for purposes of
21 determining average manufacturer price and best
22 price under this section with respect to the covered
23 outpatient drug and a rebate period and for pur-
24 poses of offsets required under subsection (b)(1)(B).

1 “(7) ASSESSMENTS AND REPORT TO CON-
2 GRESS.—

3 “(A) ASSESSMENTS.—

4 “(i) IN GENERAL.—Not later than
5 180 days after the end of each assessment
6 period of any risk-sharing value-based pay-
7 ment agreement for a State approved
8 under this subsection, the Secretary shall
9 conduct an evaluation of such agreement
10 which shall include an evaluation by the
11 Chief Actuary to determine whether pro-
12 gram spending under the risk-sharing
13 value-based payment agreement aligned
14 with the projections for the agreement
15 made under paragraph (2)(A)(ii), including
16 an assessment of whether actual Federal
17 spending under this title under the agree-
18 ment was less or more than net Federal
19 spending would have been in the absence
20 of the agreement.

21 “(ii) ASSESSMENT PERIOD.—For pur-
22 poses of clause (i)—

23 “(I) the first assessment period
24 for a risk-sharing value-based pay-
25 ment agreement shall be the period of

1 time over which payments are sched-
2 uled to be made under the agreement
3 for the first 10 individuals who are
4 administered covered outpatient drugs
5 under the agreement except that such
6 period shall not exceed the 5-year pe-
7 riod after the date on which the Sec-
8 retary approves the agreement; and

9 “(II) each subsequent assessment
10 period for a risk-sharing value-based
11 payment agreement shall be the 5-
12 year period following the end of the
13 previous assessment period.

14 “(B) RESULTS OF ASSESSMENTS.—

15 “(i) TERMINATION OPTION.—If the
16 Secretary determines as a result of the as-
17 sessment by the Chief Actuary under sub-
18 paragraph (A) that the actual Federal
19 spending under this title for any covered
20 outpatient drug that was the subject of the
21 State’s risk-sharing value-based payment
22 agreement was greater than the net Fed-
23 eral spending that would have resulted in
24 the absence of the agreement, the Sec-
25 retary may terminate approval of such

1 agreement and shall immediately conduct
2 an assessment under this paragraph of any
3 other ongoing risk-sharing value-based
4 payment agreement to which the same
5 manufacturer is a party.

6 “(ii) REPAYMENT REQUIRED.—

7 “(I) IN GENERAL.—If the Sec-
8 retary determines as a result of the
9 assessment by the Chief Actuary
10 under subparagraph (A) that the Fed-
11 eral spending under the risk-sharing
12 value-based agreement for a covered
13 outpatient drug that was subject to
14 such agreement was greater than the
15 net Federal spending that would have
16 resulted in the absence of the agree-
17 ment, the manufacturer shall repay
18 the difference to the State and Fed-
19 eral governments in a timely manner
20 as determined by the Secretary.

21 “(II) TERMINATION FOR FAIL-
22 URE TO PAY.—The failure of a manu-
23 facturer to make repayments required
24 under subclause (I) in a timely man-
25 ner shall result in immediate termi-

1 nation of all risk-sharing value-based
2 agreements to which the manufacturer
3 is a party.

4 “(III) ADDITIONAL PEN-
5 ALTIES.—In the case of a manufac-
6 turer that fails to make repayments
7 required under subclause (I), the Sec-
8 retary may treat such manufacturer
9 in the same manner as a manufac-
10 turer that fails to pay required re-
11 bates under this section, and the Sec-
12 retary may—

13 “(aa) suspend or terminate
14 the manufacturer’s rebate agree-
15 ment under this section; and

16 “(bb) pursue any other rem-
17 edy that would be available if the
18 manufacturer had failed to pay
19 required rebates under this sec-
20 tion.

21 “(C) REPORT TO CONGRESS.—Not later
22 than 5 years after the first risk-sharing value-
23 based payment agreement is approved under
24 this subsection, the Secretary shall submit to

1 Congress and make available to the public a re-
2 port that includes—

3 “(i) an assessment of the impact of
4 risk-sharing value-based payment agree-
5 ments on access for individuals who are eli-
6 gible for benefits under a State plan or
7 waiver under this title to medically nec-
8 essary covered outpatient drugs and re-
9 lated treatments;

10 “(ii) an analysis of the impact of such
11 agreements on overall State and Federal
12 spending under this title;

13 “(iii) an assessment of the impact of
14 such agreements on drug prices, including
15 launch price and price increases; and

16 “(iv) such recommendations to Con-
17 gress as the Secretary deems appropriate.

18 “(8) GUIDANCE AND REGULATIONS.—

19 “(A) IN GENERAL.—Not later than Janu-
20 ary 1, 2025, the Secretary shall issue guidance
21 to States seeking to enter into risk-sharing
22 value-based payment agreements under this
23 subsection that includes a model template for
24 such agreements. The Secretary may issue any
25 additional guidance or promulgate regulations

1 as necessary to implement and enforce the pro-
2 visions of this subsection.

3 “(B) MODEL AGREEMENTS.—

4 “(i) IN GENERAL.—If a State ex-
5 presses an interest in pursuing a risk-shar-
6 ing value-based payment agreement under
7 this subsection with a manufacturer for
8 the purchase of a covered outpatient drug,
9 the Secretary may share with such State
10 any risk-sharing value-based agreement be-
11 tween a State and the manufacturer for
12 the purchase of such drug that has been
13 approved under this subsection. While such
14 shared agreement may serve as a template
15 for a State that wishes to propose, the use
16 of a previously approved agreement shall
17 not affect the submission and approval
18 process for approval of a proposed risk-
19 sharing value-based payment agreement
20 under this subsection, including the re-
21 quirements under paragraph (2)(A).

22 “(ii) CONFIDENTIALITY.—In the case
23 of a risk-sharing value-based payment
24 agreement that is disclosed to a State by
25 the Secretary under this subparagraph and

1 that is only in effect with respect to a sin-
2 gle State, the confidentiality of information
3 provisions described in subsection
4 (b)(3)(D) shall apply to such information.

5 “(C) ~~OIG CONSULTATION.~~—

6 “(i) ~~IN GENERAL.~~—The Secretary
7 shall consult with the Office of the Inspec-
8 tor General of the Department of Health
9 and Human Services to determine whether
10 there are potential program integrity con-
11 cerns with agreement approvals or tem-
12 plates and address accordingly.

13 “(ii) ~~OIG POLICY UPDATES AS NEC-~~
14 ~~CESSARY.~~—The Inspector General of the
15 Department of Health and Human Serv-
16 ices shall review and update, as necessary,
17 any policies or guidelines of the Office of
18 the Inspector General of the Department
19 of Human Services (including policies re-
20 lated to the enforcement of section 1128B)
21 to accommodate the use of risk-sharing
22 value-based payment agreements in accord-
23 ance with this section.

24 “(9) ~~RULES OF CONSTRUCTION.~~—

1 “(A) MODIFICATIONS.—Nothing in this
2 subsection or any regulations promulgated
3 under this subsection shall prohibit a State
4 from requesting a modification from the Sec-
5 retary to the terms of a risk-sharing value-
6 based payment agreement. A modification that
7 is expected to result in any increase to pro-
8 jected net State or Federal spending under the
9 agreement shall be subject to recertification by
10 the Chief Actuary as described in paragraph
11 (2)(A)(ii) before the modification may be ap-
12 proved.

13 “(B) REBATE AGREEMENTS.—Nothing in
14 this subsection shall be construed as requiring
15 a State to enter into a risk-sharing value-based
16 payment agreement or as limiting or super-
17 seding the ability of a State to enter into a sup-
18 plemental rebate agreement for a covered out-
19 patient drug.

20 “(C) FFP FOR PAYMENTS UNDER RISK-
21 SHARING VALUE-BASED PAYMENT AGREE-
22 MENTS.—Federal financial participation shall
23 be available under this title for any payment
24 made by a State to a manufacturer for a cov-
25 ered outpatient drug under a risk-sharing

1 value-based payment agreement in accordance
2 with this subsection, except that no Federal fi-
3 nancial participation shall be available for any
4 payment made by a State to a manufacturer
5 under such an agreement on and after the ef-
6 fective date of a disapproval of such agreement
7 by the Secretary.

8 “(D) CONTINUED APPLICATION OF OTHER
9 PROVISIONS.—Except as expressly provided in
10 this subsection, nothing in this subsection or in
11 any regulations promulgated under this sub-
12 section shall affect the application of any other
13 provision of this Act.

14 “(10) APPROPRIATIONS.—For fiscal year 2023
15 and each fiscal year thereafter, there are appro-
16 priated to the Secretary \$5,000,000 for the purpose
17 of carrying out this subsection.

18 “(11) DEFINITIONS.—In this subsection:

19 “(A) CHIEF ACTUARY.—The term ‘Chief
20 Actuary’ means the Chief Actuary of the Cen-
21 ters for Medicare & Medicaid Services.

22 “(B) INSTALLMENT YEAR.—The term ‘in-
23 stallment year’ means, with respect to a risk-
24 sharing value-based payment agreement, a 12-

1 month period during which a covered outpatient
2 drug is administered under the agreement.

3 “(C) POTENTIALLY CURATIVE TREATMENT
4 INTENDED FOR ONE-TIME USE.—The term ‘po-
5 tentially curative treatment intended for one-
6 time use’ means a treatment that consists of
7 the administration of a covered outpatient drug
8 that—

9 “(i) is a form of gene therapy for a
10 rare disease, as defined by the Commis-
11 sioner of Food and Drugs, designated
12 under section 526 of the Federal Food,
13 Drug, and Cosmetics Act, and approved
14 under section 505 of such Act or licensed
15 under subsection (a) or (k) of section 351
16 of the Public Health Service Act to treat
17 a serious or life-threatening disease or con-
18 dition;

19 “(ii) if administered in accordance
20 with the labeling of such drug, is expected
21 to result in either—

22 “(I) the cure of such disease or
23 condition; or

24 “(II) a reduction in the symp-
25 toms of such disease or condition to

1 the extent that such disease or condi-
2 tion is not expected to lead to early
3 mortality; and

4 “(iii) is expected to achieve a result
5 described in clause (ii), which may be
6 achieved over an extended period of time,
7 after not more than 3 administrations.

8 “(D) RELEVANT CLINICAL PARAMETER.—
9 The term ‘relevant clinical parameter’ means,
10 with respect to a covered outpatient drug that
11 is the subject of a risk-sharing value-based pay-
12 ment agreement—

13 “(i) a clinical endpoint specified in the
14 drug’s labeling or supported by one or
15 more of the compendia described in section
16 1861(t)(2)(B)(ii)(I) that—

17 “(I) is able to be measured or
18 evaluated on an annual basis for each
19 year of the agreement on an inde-
20 pendent basis by a provider or other
21 entity; and

22 “(II) is required to be achieved
23 (based on observed metrics in patient
24 populations) under the terms of the
25 agreement; or

1 “(ii) a surrogate endpoint (as defined
2 in section 507(e)(9) of the Federal Food,
3 Drug, and Cosmetic Act), including those
4 developed by patient-focused drug develop-
5 ment tools, that—

6 “(I) is able to be measured or
7 evaluated on an annual basis for each
8 year of the agreement on an inde-
9 pendent basis by a provider or other
10 entity; and

11 “(II) has been qualified by the
12 Food and Drug Administration.

13 “(E) RISK-SHARING VALUE-BASED PAY-
14 MENT AGREEMENT.—The term ‘risk-sharing
15 value-based payment agreement’ means an
16 agreement between a State plan and a manu-
17 facturer—

18 “(i) for the purchase of a covered out-
19 patient drug of the manufacturer that is a
20 potentially curative treatment intended for
21 one-time use;

22 “(ii) under which payment for such
23 drug shall be made pursuant to an install-
24 ment-based payment structure that meets
25 the requirements of paragraph (3);

1 “(iii) which conditions payment on the
2 achievement of at least 2 relevant clinical
3 parameters (as defined in subparagraph
4 (C));

5 “(iv) which provides that—

6 “(I) the State plan will directly
7 reimburse the manufacturer for the
8 drug; or

9 “(II) a third party will reimburse
10 the manufacture in a manner ap-
11 proved by the Secretary;

12 “(v) is approved by the Secretary in
13 accordance with paragraph (2).

14 “(F) TOTAL INSTALLMENT YEAR
15 AMOUNT.—The term ‘total installment year
16 amount’ means, with respect to a risk-sharing
17 value-based payment agreement for the pur-
18 chase of a covered outpatient drug and an in-
19 stallment year, an amount equal to the product
20 of—

21 “(i) the unit price of the drug charged
22 under the agreement; and

23 “(ii) the number of units of such drug
24 administered under the agreement during
25 such installment year.”.

1 (b) CONFORMING AMENDMENTS.—

2 (1) Section 1903(i)(10)(A) of the Social Secu-
3 rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by
4 striking “or unless section 1927(a)(3) applies” and
5 inserting “, section 1927(a)(3) applies with respect
6 to such drugs, or such drugs are the subject of a
7 risk-sharing value-based payment agreement under
8 section 1927(l)”.

9 (2) Section 1927(b) of the Social Security Act
10 (42 U.S.C. 1396r–8(b)) is amended—

11 (A) in paragraph (1)(A), by inserting “(ex-
12 cept for drugs for which payment is made by a
13 State under a risk-sharing value-based payment
14 agreement under subsection (l))” after “under
15 the State plan for such period”; and

16 (B) in paragraph (3)—

17 (i) in subparagraph (C)(i), by insert-
18 ing “or subsection (l)(2)(A)” after “sub-
19 paragraph (A)”;

20 (ii) in subparagraph (D), in the mat-
21 ter preceding clause (i), by inserting “,
22 under subsection (l)(2)(A),” after “under
23 this paragraph”.

1 **SEC. 307. MODIFICATION OF MAXIMUM REBATE AMOUNT**
2 **UNDER MEDICAID DRUG REBATE PROGRAM.**

3 (a) IN GENERAL.—Subparagraph (D) of section
4 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–
5 8(c)(2)) is amended to read as follows:

6 “(D) MAXIMUM REBATE AMOUNT.—

7 “(i) IN GENERAL.—Except as pro-
8 vided in clause (ii), in no case shall the
9 sum of the amounts applied under para-
10 graph (1)(A)(ii) and this paragraph with
11 respect to each dosage form and strength
12 of a single source drug or an innovator
13 multiple source drug for a rebate period
14 exceed—

15 “(I) for rebate periods beginning
16 after December 31, 2009, and before
17 September 30, 2025, 100 percent of
18 the average manufacturer price of the
19 drug; and

20 “(II) for rebate periods beginning
21 on or after October 1, 2025, 125 per-
22 cent of the average manufacturer
23 price of the drug.

24 “(ii) NO MAXIMUM AMOUNT FOR
25 DRUGS IF AMP INCREASES OUTPACE IN-
26 FLATION.—

1 “(I) IN GENERAL.—If the aver-
2 age manufacturer price with respect
3 to each dosage form and strength of
4 a single source drug or an innovator
5 multiple source drug increases on or
6 after October 1, 2024, and such in-
7 creased average manufacturer price
8 exceeds the inflation-adjusted average
9 manufacturer price determined with
10 respect to such drug under subclause
11 (II) for the rebate period, clause (i)
12 shall not apply and there shall be no
13 limitation on the sum of the amounts
14 applied under paragraph (1)(A)(ii)
15 and this paragraph for the rebate pe-
16 riod with respect to each dosage form
17 and strength of the single source drug
18 or innovator multiple source drug.

19 “(II) INFLATION-ADJUSTED AV-
20 ERAGE MANUFACTURER PRICE DE-
21 FINED.—In this clause, the term ‘in-
22 flation-adjusted average manufacturer
23 price’ means, with respect to a single
24 source drug or an innovator multiple
25 source drug and a rebate period, the

1 average manufacturer price for each
2 dosage form and strength of the drug
3 for the calendar quarter beginning
4 July 1, 1990 (without regard to
5 whether or not the drug has been sold
6 or transferred to an entity, including
7 a division or subsidiary of the manu-
8 facturer, after the 1st day of such
9 quarter), increased by the percentage
10 by which the consumer price index for
11 all urban consumers (United States
12 city average) for the month before the
13 month in which the rebate period be-
14 gins exceeds such index for September
15 1990.”.

16 (b) TREATMENT OF SUBSEQUENTLY APPROVED
17 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act
18 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting
19 “and clause (ii)(II) of subparagraph (D)” after “clause
20 (ii)(II) of subparagraph (A)”.

21 (c) TECHNICAL AMENDMENTS.—Section
22 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42
23 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

24 (1) by striking “subparagraph (A)” and insert-
25 ing “paragraph (3)(A)”; and

1 (2) by striking “this subparagraph” and insert-
2 ing “paragraph (3)(C)”.

3 **TITLE IV—ADDRESSING INTER-**
4 **MEDIARIES & DRUG COM-**
5 **PETITION**

6 **SEC. 401. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
7 **EFIT MANAGER SERVICES.**

8 Subpart II of part A of title XXVII of the Public
9 Health Service Act (42 U.S.C. 300gg–11 et seq.) is
10 amended by adding at the end the following:

11 **“SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY**
12 **BENEFIT MANAGER SERVICES.**

13 “(a) IN GENERAL.—A group health plan or health
14 insurance issuer offering group or individual health insur-
15 ance coverage or an entity or subsidiary providing phar-
16 macy benefits management services shall not enter into
17 a contract with a drug manufacturer, distributor, whole-
18 saler, subcontractor, rebate aggregator, or any associated
19 third party that limits the disclosure of information to
20 plan sponsors in such a manner that prevents the plan
21 or coverage, or an entity or subsidiary providing pharmacy
22 benefits management services on behalf of a plan or cov-
23 erage from making the reports described in subsection (b).

24 “(b) REPORTS TO GROUP PLAN SPONSORS.—

1 “(1) IN GENERAL.—Beginning with the first
2 plan year that begins after the date of enactment of
3 this section, not less frequently than once every six
4 months, a health insurance issuer offering group
5 health insurance coverage or an entity providing
6 pharmacy benefits management services on behalf of
7 a group health plan shall submit to the self-funded
8 group health plan and at the request of any other
9 group health plan a report in accordance with this
10 subsection and make such report available to the
11 plan sponsor in a machine-readable format. Each
12 such report shall include, with respect to the applica-
13 ble group health plan or health insurance coverage—

14 “(A) information collected from drug man-
15 ufacturers by such issuer or entity on the total
16 amount of copayment assistance dollars paid, or
17 copayment cards applied, that were funded by
18 the drug manufacturer with respect to the en-
19 rollees in such plan or coverage;

20 “(B) a list of each covered drug dispensed
21 during the reporting period, including, with re-
22 spect to each such drug during the reporting
23 period—

24 “(i) the brand name, chemical entity,
25 and National Drug Code;

1 “(ii) the number of enrollees for
2 whom the drug was filled during the plan
3 year, the total number of prescription fills
4 for the drug (including original prescrip-
5 tions and refills), and the total number of
6 dosage units of the drug dispensed across
7 the plan year, including whether the dis-
8 pensing channel was by retail, mail order,
9 or specialty pharmacy;

10 “(iii) the wholesale acquisition cost,
11 listed as cost per days supply and cost per
12 pill, or in the case of a drug in another
13 form, per dose;

14 “(iv) the total out-of-pocket spending
15 by enrollees on such drug, including en-
16 rollee spending through copayments, coin-
17 surance, and deductibles; and

18 “(v) for any drug for which gross
19 spending of the group health plan or
20 health insurance coverage exceeded
21 \$10,000 during the reporting period—

22 “(I) a list of all other available
23 drugs in the same therapeutic cat-
24 egory or class, including brand name
25 drugs and biological products and ge-

1 neric drugs or biosimilar biological
2 products that are in the same thera-
3 peutic category or class; and

4 “(II) the rationale for preferred
5 formulary placement of a particular
6 drug or drugs in that therapeutic cat-
7 egory or class;

8 “(C) a list of each therapeutic category or
9 class of drugs that were dispensed under the
10 health plan or health insurance coverage during
11 the reporting period, and, with respect to each
12 such therapeutic category or class of drugs,
13 during the reporting period—

14 “(i) total gross spending by the plan,
15 before manufacturer rebates, fees, or other
16 manufacturer remuneration;

17 “(ii) the number of enrollees who
18 filled a prescription for a drug in that cat-
19 egory or class;

20 “(iii) if applicable to that category or
21 class, a description of the formulary tiers
22 and utilization mechanisms (such as prior
23 authorization or step therapy) employed
24 for drugs in that category or class;

1 “(iv) the total out-of-pocket spending
2 by enrollees, including enrollee spending
3 through copayments, coinsurance, and
4 deductibles; and

5 “(v) for each therapeutic category or
6 class under which three or more drugs are
7 marketed and available—

8 “(I) the amount received, or ex-
9 pected to be received, from drug man-
10 ufacturers in rebates, fees, alternative
11 discounts, or other remuneration—

12 “(aa) to be paid by drug
13 manufacturers for claims in-
14 curred during the reporting pe-
15 riod; or

16 “(bb) that is related to utili-
17 zation of drugs, in such thera-
18 peutic category or class;

19 “(II) the total net spending by
20 the health plan or health insurance
21 coverage on that category or class of
22 drugs; and

23 “(III) the net price per dosage
24 unit or course of treatment incurred
25 by the health plan or health insurance

1 coverage and its enrollees, after man-
2 ufacturer rebates, fees, and other re-
3 munerations for drugs dispensed within
4 such therapeutic category or class
5 during the reporting period;

6 “(D) total gross spending on prescription
7 drugs by the plan or coverage during the re-
8 porting period, before rebates and other manu-
9 facturer fees or remuneration;

10 “(E) total amount received, or expected to
11 be received, by the health plan or health insur-
12 ance coverage in drug manufacturer rebates,
13 fees, alternative discounts, and all other remu-
14 neration received from the manufacturer or any
15 third party related to utilization of drug or
16 drug spending under that health plan or health
17 insurance coverage during the reporting period;

18 “(F) the total net spending on prescription
19 drugs by the health plan or health insurance
20 coverage during the reporting period; and

21 “(G) amounts paid directly or indirectly in
22 rebates, fees, or any other type of remuneration
23 to brokers, consultants, advisors, or any other
24 individual or firm who referred the group health

1 plan’s or health insurance issuer’s business to
2 the pharmacy benefit manager.

3 “(2) PRIVACY REQUIREMENTS.—Health insur-
4 ance issuers offering group health insurance cov-
5 erage and entities providing pharmacy benefits man-
6 agement services on behalf of a group health plan
7 shall provide information under paragraph (1) in a
8 manner consistent with the privacy, security, and
9 breach notification regulations promulgated under
10 section 264(c) of the Health Insurance Portability
11 and Accountability Act of 1996 (or successor regula-
12 tions), and shall restrict the use and disclosure of
13 such information according to such privacy regula-
14 tions.

15 “(3) DISCLOSURE AND REDISCLOSURE.—

16 “(A) LIMITATION TO BUSINESS ASSOCI-
17 ATES.—A group health plan receiving a report
18 under paragraph (1) may disclose such informa-
19 tion only to business associates of such plan as
20 defined in section 160.103 of title 45, Code of
21 Federal Regulations (or successor regulations).

22 “(B) CLARIFICATION REGARDING PUBLIC
23 DISCLOSURE OF INFORMATION.—Nothing in
24 this section prevents a health insurance issuer
25 offering group health insurance coverage or an

1 entity providing pharmacy benefits management
2 services on behalf of a group health plan from
3 placing reasonable restrictions on the public dis-
4 closure of the information contained in a report
5 described in paragraph (1).

6 “(c) ENFORCEMENT.—

7 “(1) IN GENERAL.—The Secretary, in consulta-
8 tion with the Secretary of Labor and the Secretary
9 of the Treasury, shall enforce this section.

10 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
11 TION.—A health insurance issuer or an entity pro-
12 viding pharmacy benefit management services that
13 violates subsection (a) or fails to provide information
14 required under subsection (b) or a drug manufac-
15 turer that fails to provide information under sub-
16 section (b)(1)(A), in a timely manner shall be sub-
17 ject to a civil monetary penalty in the amount of
18 \$10,000 for each day during which such violation
19 continues or such information is not disclosed or re-
20 ported.

21 “(3) FALSE INFORMATION.—A health insurance
22 issuer, entity providing pharmacy benefit manage-
23 ment services, or drug manufacturer that knowingly
24 provides false information under this section shall be
25 subject to a civil money penalty in an amount not

1 to exceed \$100,000 for each item of false informa-
2 tion. Such civil money penalty shall be in addition to
3 other penalties as may be prescribed by law.

4 “(4) PROCEDURE.—The provisions of section
5 1128A of the Social Security Act, other than sub-
6 sections (a) and (b) and the first sentence of sub-
7 section (c)(1) of such section shall apply to civil
8 monetary penalties under this subsection in the
9 same manner as such provisions apply to a penalty
10 or proceeding under section 1128A of the Social Se-
11 curity Act.

12 “(5) SAFE HARBOR.—The Secretary may waive
13 penalties under paragraph (2), or extend the period
14 of time for compliance with a requirement of this
15 section, for an entity in violation of this section that
16 has made a good-faith effort to comply with this sec-
17 tion.

18 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to prohibit entities providing phar-
20 macy benefits management services from retaining bona
21 fide service fees, provided that such fees are transparent
22 to group health plans and health insurance issuers and
23 are not linked directly to the price or formulary placement
24 or position of a drug.

25 “(e) DEFINITIONS.—In this section—

1 “(1) the term ‘similarly situated pharmacy’
2 means, with respect to a particular pharmacy, an-
3 other pharmacy that is approximately the same size
4 (as measured by the number of prescription drugs
5 dispensed), and that serves patients in the same geo-
6 graphical area, whether through physical locations or
7 mail order;

8 “(2) the term ‘wholesale acquisition cost’ has
9 the meaning given such term in section
10 1847A(c)(6)(B) of the Social Security Act; and

11 “(3) the term ‘bona fide service fees’ means
12 fees paid by a manufacturer, customer, or client
13 (other than a group health plan or health insurance
14 issuer) of an entity providing pharmacy benefit man-
15 agement services, to an entity providing pharmacy
16 benefit management services, that represent fair
17 market value for bona fide, itemized services actually
18 performed on behalf of the manufacturer, customer,
19 or client would otherwise perform or contract for in
20 the absence of the service arrangement, without
21 prior consent for any specific arrangements.”.

22 **SEC. 402. STUDY OF PHARMACEUTICAL SUPPLY CHAIN**
23 **INTERMEDIARIES AND MERGER ACTIVITY.**

24 (a) INITIAL REPORT.—Not later than 1 year after
25 the date of enactment of this Act, the Commission shall

1 submit to the appropriate committees of Congress a report
2 that—

3 (1) addresses at minimum—

4 (A) whether pharmacy benefit managers—

5 (i) charge payers a higher price than
6 the reimbursement rate at which the phar-
7 macy benefit managers reimburse com-
8 peting pharmacies;

9 (ii) steer patients for anticompetitive
10 purposes to any pharmacies, including re-
11 tail, mail-order, or any other type of phar-
12 macy, in which the pharmacy benefit man-
13 ager has an ownership interest;

14 (iii) audit or review proprietary data,
15 including acquisition costs, patient infor-
16 mation, or dispensing information, of com-
17 peting pharmacies that can be used for
18 anticompetitive purposes; or

19 (iv) use formulary designs to increase
20 the market share of higher cost prescrip-
21 tion drugs and depress the market share of
22 lower cost prescription drugs (each net of
23 rebates and discounts);

24 (B) how companies and payers assess the
25 benefits, costs, and risks of contracting with

1 intermediaries, including pharmacy services ad-
2 ministrative organizations, and whether more
3 information about the roles of intermediaries
4 should be available to consumers and payers;
5 and

6 (C) whether there are any specific legal or
7 regulatory obstacles the Commission currently
8 faces in ensuring a competitive and transparent
9 marketplace in the pharmaceutical supply
10 chain, including the pharmacy benefit manager
11 marketplace and pharmacy services administra-
12 tive organizations; and

13 (2) provides—

14 (A) observations or conclusions drawn
15 from the November 2017 roundtable entitled
16 “Understanding Competition in Prescription
17 Drug Markets: Entry and Supply Chain Dy-
18 namics”, and any similar efforts;

19 (B) specific actions the Commission in-
20 tends to take as a result of the November 2017
21 roundtable, and any similar efforts, including a
22 detailed description of relevant forthcoming ac-
23 tions, additional research or roundtable discus-
24 sions, consumer education efforts, or enforce-
25 ment actions; and

1 (C) policy or legislative recommendations
2 to—

3 (i) improve transparency and competi-
4 tion in the pharmaceutical supply chain;

5 (ii) prevent and deter anticompetitive
6 behavior in the pharmaceutical supply
7 chain; and

8 (iii) best ensure that consumers ben-
9 efit from any cost savings or efficiencies
10 that may result from mergers and consoli-
11 dations.

12 (b) INTERIM REPORT.—Not later than 180 days
13 after the date of enactment of this Act, the Commission
14 shall submit to the appropriate committees of Congress
15 an interim report on the progress of the report required
16 by subsection (a), along with preliminary findings and
17 conclusions based on information collected to that date.

18 (c) DEFINITIONS.—In this section:

19 (1) APPROPRIATE COMMITTEES OF CON-
20 GRESS.—The term “appropriate committees of Con-
21 gress” means—

22 (A) the Committee on Energy and Com-
23 merce of the House of Representatives;

24 (B) the Committee on the Judiciary of the
25 Senate; and

1 (C) the Committee on the Judiciary of the
2 House of Representatives.

3 (2) COMMISSION.—The term “Commission”
4 means the Federal Trade Commission.

5 **SEC. 403. REQUIREMENT THAT DIRECT-TO-CONSUMER AD-**
6 **VERTISEMENTS FOR PRESCRIPTION DRUGS**
7 **AND BIOLOGICAL PRODUCTS INCLUDE**
8 **TRUTHFUL AND NON-MISLEADING PRICING**
9 **INFORMATION.**

10 Part A of title XI of the Social Security Act is
11 amended by adding at the end the following new section:

12 **“SEC. 1150D. REQUIREMENT THAT DIRECT-TO-CONSUMER**
13 **ADVERTISEMENTS FOR PRESCRIPTION**
14 **DRUGS AND BIOLOGICAL PRODUCTS IN-**
15 **CLUDE TRUTHFUL AND NON-MISLEADING**
16 **PRICING INFORMATION.**

17 “(a) IN GENERAL.—The Secretary shall require that
18 each direct-to-consumer advertisement for a prescription
19 drug or biological product for which payment is available
20 under title XVIII or XIX includes an appropriate disclo-
21 sure of truthful and non-misleading pricing information
22 with respect to the drug or product.

23 “(b) DETERMINATION BY CMS.—The Secretary, act-
24 ing through the Administrator of the Centers for Medicare
25 & Medicaid Services, shall determine the components of

1 the requirement under subsection (a), such as the forms
2 of advertising, the manner of disclosure, the price point
3 listing, and the price information for disclosure.”.

4 **SEC. 404. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**
5 **SIVITY TO SPUR ACCESS AND COMPETITION.**

6 Clause (iv) of section 505(j)(5)(B) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B))
8 is amended—

9 (1) in subclause (I), after “180 days after the
10 date of the first commercial marketing of the drug
11 (including the commercial marketing of the listed
12 drug) by any first applicant” by inserting “or by an
13 applicant whose application is approved pursuant to
14 subclause (III)”;

15 (2) by adding at the end the following new sub-
16 clause:

17 “(III) APPLICANT APPROVAL.—An applica-
18 tion containing a certification described in para-
19 graph (2)(A)(vii)(IV) that is for a drug for
20 which a first applicant has submitted an appli-
21 cation containing such a certification can be ap-
22 proved notwithstanding the eligibility of a first
23 applicant for the 180-day exclusivity period de-
24 scribed in subclause (II)(aa) if each of the fol-
25 lowing conditions is met:

1 “(aa) The approval of such an appli-
2 cation could be made effective, but for the
3 eligibility of a first applicant for 180-day
4 exclusivity under this clause.

5 “(bb) At least 30 months have passed
6 since the date of submission of an applica-
7 tion for the drug by at least one first ap-
8 plicant.

9 “(cc) Approval of an application for
10 the drug submitted by at least one first ap-
11 plicant is not precluded under clause (iii).

12 “(dd) No application for the drug
13 submitted by any first applicant is ap-
14 proved at the time the conditions under
15 items (aa), (bb), and (cc) are all met, re-
16 gardless of whether such an application is
17 subsequently approved.”.

18 **SEC. 405. ENDING THE PRACTICE PREVENTING MARKET**
19 **COMPETITION KNOWN AS “PAY-FOR-DELAY”.**

20 (a) CONGRESSIONAL FINDINGS AND DECLARATION
21 OF PURPOSES.—

22 (1) FINDINGS.—Congress finds the following:

23 (A) In 1984, the Drug Price Competition
24 and Patent Term Restoration Act (Public Law
25 98–417) (referred to in this Act as the “1984

1 Act”), was enacted with the intent of facili-
2 tating the early entry of generic drugs while
3 preserving incentives for innovation.

4 (B) Prescription drugs make up approxi-
5 mately 10 percent of the national health care
6 spending.

7 (C) Initially, the 1984 Act was successful
8 in facilitating generic competition to the benefit
9 of consumers and health care payers, although
10 88 percent of all prescriptions dispensed in the
11 United States are generic drugs, they account
12 for only 28 percent of all expenditures.

13 (D) Generic drugs cost substantially less
14 than brand name drugs, with discounts off the
15 brand price averaging 80 to 85 percent.

16 (E) Federal dollars currently account for
17 over 40 percent of the \$325,000,000,000 spent
18 on retail prescription drugs, and this share is
19 expected to rise to 47 percent by 2025.

20 (F)(i) In recent years, the intent of the
21 1984 Act has been subverted by certain settle-
22 ment agreements in which brand name compa-
23 nies transfer value to their potential generic
24 competitors to settle claims that the generic

1 company is infringing the branded company's
2 patents.

3 (ii) These “reverse payment” settlement
4 agreements—

5 (I) allow a branded company to share
6 its monopoly profits with the generic com-
7 pany as a way to protect the branded com-
8 pany's monopoly; and

9 (II) have unduly delayed the mar-
10 keting of low-cost generic drugs contrary
11 to free competition, the interests of con-
12 sumers, and the principles underlying anti-
13 trust law.

14 (iii) Because of the price disparity between
15 brand name and generic drugs, such agree-
16 ments are more profitable for both the brand
17 and generic manufacturers than competition
18 and will become increasingly common unless
19 prohibited.

20 (iv) These agreements result in consumers
21 losing the benefits that the 1984 Act was in-
22 tended to provide.

23 (G) In 2010, the Biologics Price Competi-
24 tion and Innovation Act (Public Law 111–148)
25 (referred to in this Act as the “BPCIA”), was

1 enacted with the intent of facilitating the early
2 entry of biosimilar and interchangeable follow-
3 on versions of branded biological products while
4 preserving incentives for innovation.

5 (H) Biological drugs play an important
6 role in treating many serious illnesses, from
7 cancers to genetic disorders. They are also ex-
8 pensive, representing more than 40 percent of
9 all prescription drug spending.

10 (I) Competition from biosimilar and inter-
11 changeable biological products promises to
12 lower drug costs and increase patient access to
13 biological medicines. But “reverse payment”
14 settlement agreements also threaten to delay
15 the entry of biosimilar and interchangeable bio-
16 logical products, which would undermine the
17 goals of BPCIA.

18 (2) PURPOSES.—The purposes of this Act
19 are—

20 (A) to enhance competition in the pharma-
21 ceutical market by stopping anticompetitive
22 agreements between brand name and generic
23 drug and biosimilar biological product manufac-
24 turers that limit, delay, or otherwise prevent

1 competition from generic drugs and biosimilar
2 biological products; and

3 (B) to support the purpose and intent of
4 antitrust law by prohibiting anticompetitive
5 practices in the pharmaceutical industry that
6 harm consumers.

7 (b) UNLAWFUL COMPENSATION FOR DELAY.—

8 (1) IN GENERAL.—The Federal Trade Commis-
9 sion Act (15 U.S.C. 44 et seq.) is amended by in-
10 sserting after section 26 (15 U.S.C. 57c-2) the fol-
11 lowing:

12 **“SEC. 27. PRESERVING ACCESS TO AFFORDABLE GENERICS**
13 **AND BIOSIMILARS.**

14 “(a) IN GENERAL.—

15 “(1) ENFORCEMENT PROCEEDING.—The Com-
16 mission may initiate a proceeding to enforce the pro-
17 visions of this section against the parties to any
18 agreement resolving or settling, on a final or interim
19 basis, a patent claim, in connection with the sale of
20 a drug product or biological product.

21 “(2) PRESUMPTION AND VIOLATION.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), in such a proceeding, an agreement
24 shall be presumed to have anticompetitive ef-
25 fects and shall be a violation of this section if—

1 “(i) an ANDA filer or a biosimilar bi-
2 ological product application filer receives
3 anything of value, including an exclusive li-
4 cense; and

5 “(ii) the ANDA filer or biosimilar bio-
6 logical product application filer agrees to
7 limit or forgo research, development, man-
8 ufacturing, marketing, or sales of the
9 ANDA product or biosimilar biological
10 product, as applicable, for any period of
11 time.

12 “(B) EXCEPTION.—Subparagraph (A)
13 shall not apply if the parties to such agreement
14 demonstrate by clear and convincing evidence
15 that—

16 “(i) the value described in subpara-
17 graph (A)(i) is compensation solely for
18 other goods or services that the ANDA
19 filer or biosimilar biological product appli-
20 cation filer has promised to provide; or

21 “(ii) the procompetitive benefits of the
22 agreement outweigh the anticompetitive ef-
23 fects of the agreement.

1 “(b) LIMITATIONS.—In determining whether the set-
2 tling parties have met their burden under subsection
3 (a)(2)(B), the fact finder shall not presume—

4 “(1) that entry would not have occurred until
5 the expiration of the relevant patent or statutory ex-
6 clusivity; or

7 “(2) that the agreement’s provision for entry of
8 the ANDA product or biosimilar biological product
9 prior to the expiration of the relevant patent or stat-
10 utory exclusivity means that the agreement is pro-
11 competitive.

12 “(c) EXCLUSIONS.—Nothing in this section shall pro-
13 hibit a resolution or settlement of a patent infringement
14 claim in which the consideration that the ANDA filer or
15 biosimilar biological product application filer, respectively,
16 receives as part of the resolution or settlement includes
17 only one or more of the following:

18 “(1) The right to market and secure final ap-
19 proval in the United States for the ANDA product
20 or biosimilar biological product at a date, whether
21 certain or contingent, prior to the expiration of—

22 “(A) any patent that is the basis for the
23 patent infringement claim; or

24 “(B) any patent right or other statutory
25 exclusivity that would prevent the marketing of

1 such ANDA product or biosimilar biological
2 product.

3 “(2) A payment for reasonable litigation ex-
4 penses not to exceed—

5 “(A) for calendar year 2021, \$7,500,000;
6 or

7 “(B) for calendar year 2022 and each sub-
8 sequent calendar year, the amount determined
9 for the preceding calendar year adjusted to re-
10 flect the percentage increase (if any) in the
11 Producer Price Index for Legal Services pub-
12 lished by the Bureau of Labor Statistics of the
13 Department of Labor for the most recent cal-
14 endar year.

15 “(3) A covenant not to sue on any claim that
16 the ANDA product or biosimilar biological product
17 infringes a United States patent.

18 “(d) ENFORCEMENT.—

19 “(1) ENFORCEMENT.—A violation of this sec-
20 tion shall be treated as an unfair method of competi-
21 tion under section 5(a)(1).

22 “(2) JUDICIAL REVIEW.—

23 “(A) IN GENERAL.—Any party that is sub-
24 ject to a final order of the Commission, issued
25 in an administrative adjudicative proceeding

1 under the authority of subsection (a)(1), may,
2 within 30 days of the issuance of such order,
3 petition for review of such order in—

4 “(i) the United States Court of Ap-
5 peals for the District of Columbia Circuit;

6 “(ii) the United States Court of Ap-
7 peals for the circuit in which the ultimate
8 parent entity, as defined in section
9 801.1(a)(3) of title 16, Code of Federal
10 Regulations, or any successor thereto, of
11 the NDA holder or biological product li-
12 cense holder is incorporated as of the date
13 that the NDA or biological product license
14 application, as applicable, is filed with the
15 Commissioner of Food and Drugs; or

16 “(iii) the United States Court of Ap-
17 peals for the circuit in which the ultimate
18 parent entity of the ANDA filer or bio-
19 similar biological product application filer
20 is incorporated as of the date that the
21 ANDA or biosimilar biological product ap-
22 plication is filed with the Commissioner of
23 Food and Drugs.

24 “(B) TREATMENT OF FINDINGS.—In a
25 proceeding for judicial review of a final order of

1 the Commission, the findings of the Commis-
2 sion as to the facts, if supported by evidence,
3 shall be conclusive.

4 “(e) ANTITRUST LAWS.—Nothing in this section
5 shall modify, impair, limit, or supersede the applicability
6 of the antitrust laws as defined in subsection (a) of the
7 first section of the Clayton Act (15 U.S.C. 12(a)), and
8 of section 5 of this Act to the extent that section 5 applies
9 to unfair methods of competition. Nothing in this section
10 shall modify, impair, limit, or supersede the right of an
11 ANDA filer or biosimilar biological product application
12 filer to assert claims or counterclaims against any person,
13 under the antitrust laws or other laws relating to unfair
14 competition.

15 “(f) PENALTIES.—

16 “(1) FORFEITURE.—Each party that violates or
17 assists in the violation of this section shall forfeit
18 and pay to the United States a civil penalty suffi-
19 cient to deter violations of this section, but in no
20 event greater than 3 times the value received by the
21 party that is reasonably attributable to the violation
22 of this section. If no such value has been received by
23 the NDA holder, the biological product license hold-
24 er, the ANDA filer, or the biosimilar biological prod-
25 uct application filer, the penalty to the NDA holder,

1 the biological product license holder, the ANDA
2 filer, or the biosimilar biological product application
3 filer shall be sufficient to deter violations, but in no
4 event shall be greater than 3 times the value given
5 to an ANDA filer or biosimilar biological product
6 application filer reasonably attributable to the viola-
7 tion of this section. Such penalty shall accrue to the
8 United States and may be recovered in a civil action
9 brought by the Commission, in its own name by any
10 of its attorneys designated by it for such purpose, in
11 a district court of the United States against any
12 party that violates this section. In such actions, the
13 United States district courts are empowered to grant
14 mandatory injunctions and such other and further
15 equitable relief as they deem appropriate.

16 “(2) CEASE AND DESIST.—

17 “(A) IN GENERAL.—If the Commission has
18 issued a cease and desist order with respect to
19 a party in an administrative adjudicative pro-
20 ceeding under the authority of subsection
21 (a)(1), an action brought pursuant to para-
22 graph (1) may be commenced against such
23 party at any time before the expiration of 1
24 year after such order becomes final pursuant to
25 section 5(g).

1 “(B) EXCEPTION.—In an action under
2 subparagraph (A), the findings of the Commis-
3 sion as to the material facts in the administra-
4 tive adjudicative proceeding with respect to the
5 violation of this section by a party shall be con-
6 clusive unless—

7 “(i) the terms of such cease and de-
8 sist order expressly provide that the Com-
9 mission’s findings shall not be conclusive;
10 or

11 “(ii) the order became final by reason
12 of section 5(g)(1), in which case such find-
13 ing shall be conclusive if supported by evi-
14 dence.

15 “(3) CIVIL PENALTY.—In determining the
16 amount of the civil penalty described in this section,
17 the court shall take into account—

18 “(A) the nature, circumstances, extent,
19 and gravity of the violation;

20 “(B) with respect to the violator, the de-
21 gree of culpability, any history of violations, the
22 ability to pay, any effect on the ability to con-
23 tinue doing business, profits earned by the
24 NDA holder, the biological product license hold-
25 er, the ANDA filer, or the biosimilar biological

1 product application filer, compensation received
2 by the ANDA filer or biosimilar biological prod-
3 uct application filer, and the amount of com-
4 merce affected; and

5 “(C) other matters that justice requires.

6 “(4) REMEDIES IN ADDITION.—Remedies pro-
7 vided in this subsection are in addition to, and not
8 in lieu of, any other remedy provided by Federal
9 law. Nothing in this paragraph shall be construed to
10 affect any authority of the Commission under any
11 other provision of law.

12 “(g) DEFINITIONS.—In this section:

13 “(1) AGREEMENT.—The term ‘agreement’
14 means anything that would constitute an agreement
15 under section 1 of the Sherman Act (15 U.S.C. 1)
16 or section 5 of this Act.

17 “(2) AGREEMENT RESOLVING OR SETTLING A
18 PATENT INFRINGEMENT CLAIM.—The term ‘agree-
19 ment resolving or settling a patent infringement
20 claim’ includes any agreement that is entered into
21 within 30 days of the resolution or the settlement of
22 the claim, or any other agreement that is contingent
23 upon, provides a contingent condition for, or is oth-
24 erwise related to the resolution or settlement of the
25 claim.

1 “(3) ANDA.—The term ‘ANDA’ means an ab-
2 breviated new drug application filed under section
3 505(j) of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 355(j)) or a new drug application filed
5 under section 505(b)(2) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355(b)(2)).

7 “(4) ANDA FILER.—The term ‘ANDA filer’
8 means a party that owns or controls an ANDA filed
9 with the Food and Drug Administration or has the
10 exclusive rights under such ANDA to distribute the
11 ANDA product.

12 “(5) ANDA PRODUCT.—The term ‘ANDA
13 product’ means the product to be manufactured
14 under the ANDA that is the subject of the patent
15 infringement claim.

16 “(6) BIOLOGICAL PRODUCT.—The term ‘bio-
17 logical product’ has the meaning given such term in
18 section 351(i)(1) of the Public Health Service Act
19 (42 U.S.C. 262(i)(1)).

20 “(7) BIOLOGICAL PRODUCT LICENSE APPLICA-
21 TION.—The term ‘biological product license applica-
22 tion’ means an application under section 351(a) of
23 the Public Health Service Act (42 U.S.C. 262(a)).

1 “(8) BIOLOGICAL PRODUCT LICENSE HOLD-
2 ER.—The term ‘biological product license holder’
3 means—

4 “(A) the holder of an approved biological
5 product license application for a biological prod-
6 uct;

7 “(B) a person owning or controlling en-
8 forcement of any patents that claim the biologi-
9 cal product that is the subject of such approved
10 application; or

11 “(C) the predecessors, subsidiaries, divi-
12 sions, groups, and affiliates controlled by, con-
13 trolling, or under common control with any of
14 the entities described in subparagraphs (A) and
15 (B) (such control to be presumed by direct or
16 indirect share ownership of 50 percent or great-
17 er), as well as the licensees, licensors, succes-
18 sors, and assigns of each of the entities.

19 “(9) BIOSIMILAR BIOLOGICAL PRODUCT.—The
20 term ‘biosimilar biological product’ means the prod-
21 uct to be manufactured under the biosimilar biologi-
22 cal product application that is the subject of the pat-
23 ent infringement claim.

24 “(10) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
25 CATION.—The term ‘biosimilar biological product ap-

1 plication’ means an application under section 351(k)
2 of the Public Health Service Act (42 U.S.C. 262(k))
3 for licensure of a biological product as biosimilar to,
4 or interchangeable with, a reference product.

5 “(11) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-
6 CATION FILER.—The term ‘biosimilar biological
7 product application filer’ means a party that owns or
8 controls a biosimilar biological product application
9 filed with the Food and Drug Administration or has
10 the exclusive rights under such application to dis-
11 tribute the biosimilar biological product.

12 “(12) DRUG PRODUCT.—The term ‘drug prod-
13 uct’ has the meaning given such term in section
14 314.3(b) of title 21, Code of Federal Regulations (or
15 any successor regulation).

16 “(13) MARKET.—The term ‘market’ means the
17 promotion, offering for sale, selling, or distribution
18 of a drug product.

19 “(14) NDA.—The term ‘NDA’ means a new
20 drug application filed under section 505(b) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(b)).

23 “(15) NDA HOLDER.—The term ‘NDA holder’
24 means—

1 “(A) the holder of an approved NDA appli-
2 cation for a drug product;

3 “(B) a person owning or controlling en-
4 forcement of the patent listed in the Approved
5 Drug Products With Therapeutic Equivalence
6 Evaluations (commonly known as the ‘FDA Or-
7 ange Book’) in connection with the NDA; or

8 “(C) the predecessors, subsidiaries, divi-
9 sions, groups, and affiliates controlled by, con-
10 trolling, or under common control with any of
11 the entities described in subparagraphs (A) and
12 (B) (such control to be presumed by direct or
13 indirect share ownership of 50 percent or great-
14 er), as well as the licensees, licensors, succes-
15 sors, and assigns of each of the entities.

16 “(16) PARTY.—The term ‘party’ means any
17 person, partnership, corporation, or other legal enti-
18 ty.

19 “(17) PATENT INFRINGEMENT.—The term
20 ‘patent infringement’ means infringement of any
21 patent or of any filed patent application, including
22 any extension, reissue, renewal, division, continu-
23 ation, continuation in part, reexamination, patent
24 term restoration, patents of addition, and extensions
25 thereof.

1 “(18) PATENT INFRINGEMENT CLAIM.—The
2 term ‘patent infringement claim’ means any allega-
3 tion made to an ANDA filer or biosimilar biological
4 product application filer, whether or not included in
5 a complaint filed with a court of law, that its ANDA
6 or ANDA product, or biosimilar biological product li-
7 cense application or biosimilar biological product,
8 may infringe any patent held by, or exclusively li-
9 censed to, the NDA holder, biological product license
10 holder, ANDA filer, or biosimilar biological product
11 application filer of the drug product or biological
12 product, as applicable.

13 “(19) STATUTORY EXCLUSIVITY.—The term
14 ‘statutory exclusivity’ means those prohibitions on
15 the approval of drug applications under clauses (ii)
16 through (iv) of section 505(c)(3)(E) (5- and 3-year
17 data exclusivity), section 527 (orphan drug exclu-
18 sivity), or section 505A (pediatric exclusivity) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355(c)(3)(E), 360cc, 355a), or on the licensing of
21 biological product applications under section
22 351(k)(7) (12-year exclusivity) or paragraph (2) or
23 (3) of section 351(m) (pediatric exclusivity) of the
24 Public Health Service Act (42 U.S.C. 262) or under
25 section 527 of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 360cc) (orphan drug exclu-
2 sivity).”.

3 (2) EFFECTIVE DATE.—Section 27 of the Fed-
4 eral Trade Commission Act, as added by this sec-
5 tion, shall apply to all agreements described in sec-
6 tion 27(a)(1) of that Act entered into on or after the
7 date of enactment of this Act.

8 (c) CERTIFICATION OF AGREEMENTS.—

9 (1) NOTICE OF ALL AGREEMENTS.—Section
10 1111(7) of the Medicare Prescription Drug, Im-
11 provement, and Modernization Act of 2003 (21
12 U.S.C. 355 note) is amended by inserting “, or the
13 owner of a patent for which a claim of infringement
14 could reasonably be asserted against any person for
15 making, using, offering to sell, selling, or importing
16 into the United States a biological product that is
17 the subject of a biosimilar biological product applica-
18 tion” before the period at the end.

19 (2) CERTIFICATION OF AGREEMENTS.—Section
20 1112 of the Medicare Prescription Drug, Improve-
21 ment, and Modernization Act of 2003 (21 U.S.C.
22 355 note) is amended by adding at the end the fol-
23 lowing:

24 “(d) CERTIFICATION.—The Chief Executive Officer
25 or the company official responsible for negotiating any

1 agreement under subsection (a) or (b) that is required to
2 be filed under subsection (c), within 30 days after such
3 filing, shall execute and file with the Assistant Attorney
4 General and the Commission a certification as follows: ‘I
5 declare that the following is true, correct, and complete
6 to the best of my knowledge: The materials filed with the
7 Federal Trade Commission and the Department of Justice
8 under section 1112 of subtitle B of title XI of the Medi-
9 care Prescription Drug, Improvement, and Modernization
10 Act of 2003, with respect to the agreement referenced in
11 this certification—’

12 “(1) represent the complete, final, and exclusive
13 agreement between the parties;

14 “(2) include any ancillary agreements that are
15 contingent upon, provide a contingent condition for,
16 or are otherwise related to, the referenced agree-
17 ment; and

18 “(3) include written descriptions of any oral
19 agreements, representations, commitments, or prom-
20 ises between the parties that are responsive to sub-
21 section (a) or (b) of such section 1112 and have not
22 been reduced to writing.”.

23 (d) NOTIFICATION OF AGREEMENTS.—Section 1112
24 of the Medicare Prescription Drug, Improvement, and
25 Modernization Act of 2003 (21 U.S.C. 355 note), as

1 amended by section 4(b), is further amended by adding
2 at the end the following:

3 “(e) RULE OF CONSTRUCTION.—

4 “(1) IN GENERAL.—An agreement that is re-
5 quired under subsection (a) or (b) shall include
6 agreements resolving any outstanding disputes, in-
7 cluding agreements resolving or settling a Patent
8 Trial and Appeal Board proceeding.

9 “(2) DEFINITION.—For purposes of subpara-
10 graph (A), the term ‘Patent Trial and Appeal Board
11 proceeding’ means a proceeding conducted by the
12 Patent Trial and Appeal Board of the United States
13 Patent and Trademark Office, including an inter
14 partes review instituted under chapter 31 of title 35,
15 United States Code, a post-grant review instituted
16 under chapter 32 of that title (including a pro-
17 ceeding instituted pursuant to the transitional pro-
18 gram for covered business method patents, as de-
19 scribed in section 18 of the Leahy-Smith America
20 Invents Act (35 U.S.C. 321 note)), and a derivation
21 proceeding instituted under section 135 of that
22 title.”.

23 (e) FORFEITURE OF 180-DAY EXCLUSIVITY PE-
24 RIOD.—Section 505(j)(5)(D)(i)(V) of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))

1 is amended by inserting “section 27 of the Federal Trade
2 Commission Act or” after “that the agreement has vio-
3 lated”.

4 (f) COMMISSION LITIGATION AUTHORITY.—Section
5 16(a)(2) of the Federal Trade Commission Act (15 U.S.C.
6 56(a)(2)) is amended—

7 (1) in subparagraph (D), by striking “or” after
8 the semicolon;

9 (2) in subparagraph (E), by inserting “or”
10 after the semicolon; and

11 (3) inserting after subparagraph (E) the fol-
12 lowing:

13 “(F) under section 27.”.

14 (g) REPORT ON ADDITIONAL EXCLUSION.—

15 (1) IN GENERAL.—Not later than 1 year after
16 the date of enactment of this Act, the Federal Trade
17 Commission shall submit to the Committee on the
18 Judiciary of the Senate and the Committee on the
19 Judiciary of the House of Representatives a rec-
20 ommendation, and the Commission’s basis for such
21 recommendation, regarding a potential amendment
22 to include in section 27(c) of the Federal Trade
23 Commission Act (as added by section 3 of this Act)
24 an additional exclusion for consideration granted by
25 an NDA holder to a ANDA filer or by a biological

1 product license holder to a biosimilar biological prod-
2 uct application filer as part of the resolution or set-
3 tlement, a release, waiver, or limitation of a claim
4 for damages or other monetary relief.

5 (2) DEFINITIONS.—In this section, the terms
6 “ANDA filer”, “biological product license holder”,
7 “biosimilar biological product application filer”, and
8 “NDA holder” have the meanings given such terms
9 in section 27(g) of the Federal Trade Commission
10 Act (as added by section 3 of this Act).

11 (h) STATUTE OF LIMITATIONS.—The Federal Trade
12 Commission shall commence any enforcement proceeding
13 described in section 27 of the Federal Trade Commission
14 Act, as added by section 3, except for an action described
15 in section 27(f)(2) of the Federal Trade Commission Act,
16 not later than 6 years after the date on which the parties
17 to the agreement file the certification under section
18 1112(d) of the Medicare Prescription Drug Improvement
19 and Modernization Act of 2003 (21 U.S.C. 355 note).

20 (i) SEVERABILITY.—If any provision of this Act, an
21 amendment made by this Act, or the application of such
22 provision or amendment to any person or circumstance is
23 held to be unconstitutional, the remainder of this Act, the
24 amendments made by this Act, and the application of the

1 provisions of such Act or amendments to any person or
2 circumstance shall not be affected.

3 **SEC. 406. EMPOWERING THE FTC TO PREVENT “PRODUCT**
4 **HOPPING”.**

5 (a) IN GENERAL.—The Federal Trade Commission
6 Act (15 U.S.C. 41 et seq.) is amended by inserting after
7 section 26 (15 U.S.C. 57c–2) the following:

8 **“SEC. 27. PRODUCT HOPPING.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) ABBREVIATED NEW DRUG APPLICATION.—
11 The term ‘abbreviated new drug application’ means
12 an application under subsection (b)(2) or (j) of sec-
13 tion 505 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 355).

15 “(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The
16 term ‘biosimilar biological product’ means a biologi-
17 cal product licensed under section 351(k) of the
18 Public Health Service Act (42 U.S.C. 262(k)).

19 “(3) BIOSIMILAR BIOLOGICAL PRODUCT LI-
20 CENSE APPLICATION.—The term ‘biosimilar biologi-
21 cal product license application’ means an application
22 submitted under section 351(k) of the Public Health
23 Service Act (42 U.S.C. 262(k)).

24 “(4) FOLLOW-ON PRODUCT.—The term ‘follow-
25 on product’—

1 “(A) means a drug approved through an
2 application or supplement to an application sub-
3 mitted under section 505(b) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C.
5 355(b)) or a biological product licensed through
6 an application or supplement to an application
7 submitted under section 351(a) of the Public
8 Health Service Act (42 U.S.C. 262(a)) for a
9 change, modification, or reformulation to the
10 same manufacturer’s previously approved drug
11 or biological product that treats the same med-
12 ical condition; and

13 “(B) excludes such an application or sup-
14 plement to an application for a change, modi-
15 fication, or reformulation of a drug or biological
16 product that is requested by the Secretary or
17 necessary to comply with law, including sections
18 505A and 505B of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355a, 355c).

20 “(5) GENERIC DRUG.—The term ‘generic drug’
21 means a drug approved under an application sub-
22 mitted under subsection (b)(2) or (j) of section 505
23 of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 355).

1 “(6) LISTED DRUG.—The term ‘listed drug’
2 means a drug listed under section 505(j)(7) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(7)).

5 “(7) MANUFACTURER.—The term ‘manufac-
6 turer’ means the holder, licensee, or assignee of—

7 “(A) an approved application for a drug
8 under section 505(c) of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

10 “(B) a biological product license under sec-
11 tion 351(a) of the Public Health Service Act
12 (42 U.S.C. 262(a)).

13 “(8) REFERENCE PRODUCT.—The term ‘ref-
14 erence product’ has the meaning given the term in
15 section 351(i) of the Public Health Service Act (42
16 U.S.C. 262(i)).

17 “(9) ULTIMATE PARENT ENTITY.—The term
18 ‘ultimate parent entity’ has the meaning given the
19 term in section 801.1 of title 16, Code of Federal
20 Regulations, or any successor regulation.

21 “(b) PROHIBITION ON PRODUCT HOPPING.—

22 “(1) PRIMA FACIE.—Except as provided in
23 paragraph (2), a manufacturer of a reference prod-
24 uct or listed drug shall be considered to have en-
25 gaged in an unfair method of competition in or af-

1 fecting commerce in violation of section 5(a) if the
2 Commission demonstrates by a preponderance of the
3 evidence in a proceeding initiated by the Commission
4 under subsection (c)(1)(A), or in a suit brought
5 under subparagraph (B) or (C) of subsection (c)(1),
6 that, during the period beginning on the date on
7 which the manufacturer of the reference product or
8 listed drug first receives notice that an applicant has
9 submitted to the Commissioner of Food and Drugs
10 an abbreviated new drug application or biosimilar bi-
11 ological product license application and ending on
12 the date that is 180 days after the date on which
13 that generic drug or biosimilar biological product is
14 first marketed, the manufacturer engaged in either
15 of the following actions:

16 “(A) The manufacturer engaged in a hard
17 switch, which shall be established by dem-
18 onstrating that the manufacturer engaged in ei-
19 ther of the following actions:

20 “(i) Upon the request of the manufac-
21 turer of the listed drug or reference prod-
22 uct, the Commissioner of Food and Drugs
23 withdrew the approval of the application
24 for the listed drug or reference product or
25 placed the listed drug or reference product

1 on the discontinued products list and the
2 manufacturer marketed or sold a follow-on
3 product.

4 “(ii) The manufacturer of the listed
5 drug or reference product—

6 “(I)(aa) announced withdrawal
7 of, discontinuance of the manufacture
8 of, or intent to withdraw the applica-
9 tion with respect to the drug or ref-
10 erence product in a manner that im-
11 pedes competition from a generic drug
12 or a biosimilar biological product, as
13 established by objective circumstances;
14 or

15 “(bb) destroyed the inventory of
16 the listed drug or reference product in
17 a manner that impedes competition
18 from a generic drug or a biosimilar bi-
19 ological product, which may be estab-
20 lished by objective circumstances; and

21 “(II) marketed or sold a follow-
22 on product.

23 “(B) The manufacturer engaged in a soft
24 switch, which shall be established by dem-

1 onstrating that the manufacturer engaged in
2 both of the following actions:

3 “(i) The manufacturer took actions
4 with respect to the listed drug or reference
5 product other than those described in sub-
6 paragraph (A) that unfairly disadvantage
7 the listed drug or reference product rel-
8 ative to the follow-on product described in
9 clause (ii) in a manner that impedes com-
10 petition from a generic drug or a bio-
11 similar biological product that is highly
12 similar to, and has no clinically meaningful
13 difference with respect to safety, purity,
14 and potency from, the reference product,
15 which may be established by objective cir-
16 cumstances.

17 “(ii) The manufacturer marketed or
18 sold a follow-on product.

19 “(2) JUSTIFICATION.—

20 “(A) IN GENERAL.—Subject to paragraph
21 (3), the actions described in paragraph (1) by
22 a manufacturer of a listed drug or reference
23 product shall not be considered to be an unfair
24 method of competition in or affecting commerce
25 if—

1 “(i) the manufacturer demonstrates to
2 the Commission or a district court of the
3 United States, as applicable, by a prepon-
4 derance of the evidence in a proceeding ini-
5 tiated by the Commission under subsection
6 (c)(1)(A), or in a suit brought under sub-
7 paragraph (B) or (C) of subsection (c)(1),
8 that—

9 “(I) the manufacturer would
10 have taken the actions regardless of
11 whether a generic drug that ref-
12 erences the listed drug or biosimilar
13 biological product that references the
14 reference product had already entered
15 the market; and

16 “(II)(aa) with respect to a hard
17 switch under paragraph (1)(A), the
18 manufacturer took the action for rea-
19 sons relating to the safety risk to pa-
20 tients of the listed drug or reference
21 product;

22 “(bb) with respect to an action
23 described in item (aa) or (bb) of para-
24 graph (1)(A)(ii)(I), there is a supply
25 disruption that—

1 “(AA) is outside of the con-
2 trol of the manufacturer;

3 “(BB) prevents the produc-
4 tion or distribution of the appli-
5 cable listed drug or reference
6 product; and

7 “(CC) cannot be remedied
8 by reasonable efforts; or

9 “(cc) with respect to a soft
10 switch under paragraph (1)(B), the
11 manufacturer had legitimate pro-com-
12 petitive reasons, apart from the finan-
13 cial effects of reduced competition, to
14 take the action.

15 “(B) RULE OF CONSTRUCTION.—Nothing
16 in subparagraph (A) may be construed to limit
17 the information that the Commission may oth-
18 erwise obtain in any proceeding or action insti-
19 tuted with respect to a violation of this section.

20 “(3) RESPONSE.—With respect to a justifica-
21 tion offered by a manufacturer under paragraph (2),
22 the Commission may—

23 “(A) rebut any evidence presented by a
24 manufacturer during that justification; or

1 “(B) establish by a preponderance of the
2 evidence that, on balance, the pro-competitive
3 benefits from the conduct described in subpara-
4 graph (A) or (B) of paragraph (1), as applica-
5 ble, do not outweigh any anticompetitive effects
6 of the conduct, even in consideration of the jus-
7 tification so offered.

8 “(c) ENFORCEMENT.—

9 “(1) IN GENERAL.—If the Commission has rea-
10 son to believe that any manufacturer has violated, is
11 violating, or is about to violate this section, the
12 Commission may take any of the following actions:

13 “(A) Institute a proceeding—

14 “(i) that, except as provided in para-
15 graph (2), complies with the requirements
16 under section 5(b); and

17 “(ii) in which the Commission may
18 impose on the manufacturer any penalty
19 that the Commission may impose for a vio-
20 lation of section 5.

21 “(B) In the same manner and to the same
22 extent as provided in section 13(b), bring suit
23 in a district court of the United States to tem-
24 porarily enjoin the action of the manufacturer.

1 “(C) Bring suit in a district court of the
2 United States, in which the Commission may
3 seek—

4 “(i) to permanently enjoin the action
5 of the manufacturer;

6 “(ii) any of the remedies described in
7 paragraph (3); and

8 “(iii) any other equitable remedy, in-
9 cluding ancillary equitable relief.

10 “(2) JUDICIAL REVIEW.—

11 “(A) IN GENERAL.—Notwithstanding any
12 provision of section 5, any manufacturer that is
13 subject to a final order of the Commission that
14 is issued in a proceeding instituted under para-
15 graph (1)(A) may, not later than 30 days after
16 the date on which the Commission issues the
17 order, petition for review of the order in—

18 “(i) the United States Court of Ap-
19 peals for the District of Columbia Circuit;
20 or

21 “(ii) the court of appeals of the
22 United States for the circuit in which the
23 ultimate parent entity of the manufacturer
24 is incorporated.

1 “(B) TREATMENT OF FINDINGS.—In a re-
2 view of an order issued by the Commission con-
3 ducted by a court of appeals of the United
4 States under subparagraph (A), the factual
5 findings of the Commission shall be conclusive
6 if those facts are supported by the evidence.

7 “(3) EQUITABLE REMEDIES.—

8 “(A) DISGORGEMENT.—

9 “(i) IN GENERAL.—In a suit brought
10 under paragraph (1)(C), the Commission
11 may seek, and the court may order,
12 disgorgement of any unjust enrichment
13 that a person obtained as a result of the
14 violation that gives rise to the suit.

15 “(ii) CALCULATION.—Any
16 disgorgement that is ordered with respect
17 to a person under clause (i) shall be offset
18 by any amount of restitution ordered
19 under subparagraph (B).

20 “(iii) LIMITATIONS PERIOD.—The
21 Commission may seek disgorgement under
22 this subparagraph not later than 5 years
23 after the latest date on which the person
24 from which the disgorgement is sought re-
25 ceives any unjust enrichment from the ef-

1 facts of the violation that gives rise to the
2 suit in which the Commission seeks the
3 disgorgement.

4 “(B) RESTITUTION.—

5 “(i) IN GENERAL.—In a suit brought
6 under paragraph (1)(C), the Commission
7 may seek, and the court may order, res-
8 titution with respect to the violation that
9 gives rise to the suit.

10 “(ii) LIMITATIONS PERIOD.—The
11 Commission may seek restitution under
12 this subparagraph not later than 5 years
13 after the latest date on which the person
14 from which the restitution is sought re-
15 ceives any unjust enrichment from the ef-
16 fects of the violation that gives rise to the
17 suit in which the Commission seeks the
18 restitution.

19 “(4) RULES OF CONSTRUCTION.—Nothing in
20 this subsection may be construed as—

21 “(A) requiring the Commission to bring a
22 suit seeking a temporary injunction under para-
23 graph (1)(B) before bringing a suit seeking a
24 permanent injunction under paragraph (1)(C);
25 or

1 “(B) affecting any other authority of the
2 Commission under this Act to seek relief or ob-
3 tain a remedy with respect to a violation of this
4 Act.”.

5 (b) APPLICABILITY.—Section 27 of the Federal
6 Trade Commission Act, as added by subsection (a), shall
7 apply with respect to any—

8 (1) conduct that occurs on or after the date of
9 enactment of this Act; and

10 (2) action or proceeding that is commenced on
11 or after the date of enactment of this Act.

12 (c) ANTITRUST LAWS.—Nothing in this section, or
13 the amendments made by this section, shall modify, im-
14 pair, limit, or supersede the applicability of the antitrust
15 laws as defined in subsection (a) of the first section of
16 the Clayton Act (15 U.S.C. 12(a)), and of section 5 of
17 the Federal Trade Commission Act (15 U.S.C. 45) to the
18 extent that it applies to unfair methods of competition.

19 (d) RULEMAKING.—The Federal Trade Commission
20 may issue rules under section 553 of title 5, United States
21 Code, to carry out section 27 of the Federal Trade Com-
22 mission Act, as added by subsection (a), including by de-
23 fining any terms used in such section 27 (other than terms
24 that are defined in subsection (a) of such section 27).

1 **SEC. 407. PROMOTING COMPETITION BY LIMITING PATENT**
2 **THICKETS.**

3 (a) IN GENERAL.—Section 271(e) of title 35, United
4 States Code, is amended—

5 (1) in paragraph (2)(C), in the flush text fol-
6 lowing clause (ii), by adding at the end the fol-
7 lowing: “With respect to a submission described in
8 clause (ii), the act of infringement shall extend to
9 any patent that claims the biological product, a
10 method of using the biological product, or a method
11 or product used to manufacture the biological prod-
12 uct.”; and

13 (2) by adding at the end the following:

14 “(7)(A) Subject to subparagraphs (C), (D), and (E),
15 if the sponsor of an approved application for a reference
16 product, as defined in section 351(i) of the Public Health
17 Service Act (42 U.S.C. 262(i)) (referred to in this para-
18 graph as the ‘reference product sponsor’), brings an action
19 for infringement under this section against an applicant
20 for approval of a biological product under section 351(k)
21 of such Act that references that reference product (re-
22 ferred to in this paragraph as the ‘subsection (k) appli-
23 cant’), the reference product sponsor may assert in the
24 action a total of not more than 20 patents of the type
25 described in subparagraph (B), not more than 10 of which

1 shall have issued after the date specified in section
2 351(l)(7)(A) of such Act.

3 “(B) The patents described in this subparagraph are
4 patents that satisfy each of the following requirements:

5 “(i) Patents that claim the biological product
6 that is the subject of an application under section
7 351(k) of the Public Health Service Act (42 U.S.C.
8 262(k)) (or a use of that product) or a method or
9 product used in the manufacture of such biological
10 product.

11 “(ii) Patents that are included on the list of
12 patents described in section 351(l)(3)(A) of the Pub-
13 lic Health Service Act (42 U.S.C. 262(l)(3)(A)), in-
14 cluding as provided under section 351(l)(7) of such
15 Act.

16 “(iii) Patents that—

17 “(I) have an actual filing date of more
18 than 4 years after the date on which the ref-
19 erence product is approved; or

20 “(II) include a claim to a method in a
21 manufacturing process that is not used by the
22 reference product sponsor.

23 “(C) The court in which an action described in sub-
24 paragraph (A) is brought may increase the number of pat-
25 ents limited under that subparagraph—

1 “(i) if the request to increase that number is
2 made without undue delay; and

3 “(ii)(I) if the interest of justice so requires; or

4 “(II) for good cause shown, which—

5 “(aa) shall be established if the subsection
6 (k) applicant fails to provide information re-
7 quired under section 351(l)(2)(A) of the Public
8 Health Service Act (42 U.S.C. 262(l)(2)(A))
9 that would enable the reference product sponsor
10 to form a reasonable belief with respect to
11 whether a claim of infringement under this sec-
12 tion could reasonably be asserted; and

13 “(bb) may be established—

14 “(AA) if there is a material change to
15 the biological product (or process with re-
16 spect to the biological product) of the sub-
17 section (k) applicant that is the subject of
18 the application;

19 “(BB) if, with respect to a patent on
20 the supplemental list described in section
21 351(l)(7)(A) of Public Health Service Act
22 (42 U.S.C. 262(l)(7)(A)), the patent would
23 have issued before the date specified in
24 such section 351(l)(7)(A) but for the fail-
25 ure of the Office to issue the patent or a

1 delay in the issuance of the patent, as de-
2 scribed in paragraph (1) of section 154(b)
3 and subject to the limitations under para-
4 graph (2) of such section 154(b); or

5 “(CC) for another reason that shows
6 good cause, as determined appropriate by
7 the court.

8 “(D) In determining whether good cause has been
9 shown for the purposes of subparagraph (C)(ii)(II), a
10 court may consider whether the reference product sponsor
11 has provided a reasonable description of the identity and
12 relevance of any information beyond the subsection (k) ap-
13 plication that the court believes is necessary to enable the
14 court to form a belief with respect to whether a claim of
15 infringement under this section could reasonably be as-
16 serted.

17 “(E) The limitation imposed under subparagraph
18 (A)—

19 “(i) shall apply only if the subsection (k) appli-
20 cant completes all actions required under paragraphs
21 (2)(A), (3)(B)(ii), (5), (6)(C)(i), (7), and (8)(A) of
22 section 351(l) of the Public Health Service Act (42
23 U.S.C. 262(l)); and

24 “(ii) shall not apply with respect to any patent
25 that claims, with respect to a biological product, a

1 method for using that product in therapy, diagnosis,
2 or prophylaxis, such as an indication or method of
3 treatment or other condition of use.”.

4 (b) APPLICABILITY.—The amendments made by sub-
5 section (a) shall apply with respect to an application sub-
6 mitted under section 351(k) of the Public Health Service
7 Act (42 U.S.C. 262(k)) on or after the date of enactment
8 of this Act.

9 **TITLE V—BENEFICIARY COST**
10 **SHARING FAIRNESS.**

11 **SEC. 501. REPEALING OF RULE BY THE DEPARTMENT OF**
12 **HEALTH AND HUMAN SERVICES.**

13 The final rule of the Department of Health and
14 Human Services titled “Fraud And Abuse; Removal of
15 Safe Harbor Protection for Rebates Involving Prescription
16 Pharmaceuticals And Creation of New Safe Harbor Pro-
17 tection for Certain Point-of-Sale Reductions in Price on
18 Prescription Pharmaceuticals and Certain Pharmacy Ben-
19 efit Manager Service Fees; Additional Delayed Effective
20 Date” published on November 30, 2020 (85 Fed. Reg.
21 76666-76731) shall have no force or effect of law.

22 **SEC. 502. DEFINING COST UNDER PRESCRIPTION DRUG**
23 **PLANS UNDER PART D OF MEDICARE.**

24 Section 1860D–2(b)(2)(A) of the Social Security Act
25 (42 U.S.C. 1395w–102(b)(2)(A)) is amended—

1 (1) in clause (i), by inserting “of the net costs
2 to the plan, inclusive of all direct and indirect remun-
3 eration, including rebates paid by manufacturers to
4 the plan sponsor, either directly or through a phar-
5 macy benefit manager or other third party” before
6 the semicolon; and

7 (2) in clause (ii), by inserting “net” before
8 “costs”.

